NONPRESCRIPTION DRUGS ADVISORY COMMITTEE AND ARTHRITIS ADVISORY COMMITTEE

JULY 20, 1999

NDA 21070 FLEXERIL OTC SWITCH

EXECUTIVE SUMMARY

ATTACHMENT A

Attachment A

to

Executive Summary

Clinical Practice Guideline

Number 14

Acute Low Back Problems in Adults

Clinical Practice Guideline

Acute Low Back Problems in Adults

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

Executive Summary

Acute low back problems, the subject of this *Clinical Practice Guideline*, are experienced by almost everyone at some time in their adult lives. Back problems rank high among the reasons for physician office visits and are costly in terms of medical treatment, time lost from work, and nonmonetary costs such as diminished ability to perform or enjoy usual activities. For persons under age 45, low back problems are the most frequent cause of disability.

The Agency for Health Care Policy and Research (AHCPR) convened a 23-member, multidisciplinary, private-sector panel to develop a guideline for the evaluation and treatment of acute low back problems in adults. The panel included physicians, nurses, chiropractors, experts in spine research, physical therapists, a psychologist, an occupational therapist, and a consumer representative. The panel defined "back problems" as activity intolerance due to back-related symptoms and "acute" as limitations of less than 3 months' duration. Back symptoms include pain, primarily in the back, as well as back-related leg pain (sciatica). The panel agreed that the guideline should provide primary care clinicians with information on the detection of serious spinal pathology (such as tumor or infection, spinal fracture or cauda equina syndrome) as well as nonspinal pathology that could be causing limitations due to low back symptoms, but that treatment of these conditions is outside the scope of the guideline.

Furthermore, the panel agreed that the assessment and treatment of patients younger than 18 years or those with chronic low back problems (back-related limitations lasting longer than 3 months) may be quite different than for adults with acute problems. For this reason, the panel decided that back problems in children as well as chronic low back problems are also outside the scope of the guideline.

The panel's overall intent was to change the paradigm of focusing care exclusively on the pain of low back problems to one of helping patients improve their activity tolerance. Findings and recommendation statements are based on an exhaustive and systematic review and analysis of the scientific literature as well as information gathered from the clinical experience of the expert panel, public testimony, peer review, and pretesting in outpatient settings. This guideline is divided into an introduction and three chapters to correlate with the clinical approach: (1) Initial Assessment Methods; (2) Clinical Care Methods; and (3) Special Studies and Diagnostic Considerations.

Initial Assessment Methods

The initial assessment of a patient with activity intolerance due to low back symptoms consists of a focused medical history and physical examination. The primary purpose is to seek medical history responses or physical examination findings that suggest a serious underlying spinal

condition such as fracture, tumor, infection, or cauda equina syndrome. These responses or findings are referred to as "red flags." The history and physical examination should also assess for nonspinal conditions (vascular, abdominal, urinary, or pelvic pathology) causing referred low back symptoms.

Once the clinician has ruled out red flags and nonspinal pathology, the symptoms can be categorized as either sciatica or nonspecific back pain. In the absence of red flags, neither routine nor special testing is required in the first month of symptoms for either category. Most of these patients will recover spontaneously from their activity limitations within 1 month.

Clinical Care Methods

In the absence of the red flags described above, most patients with activity intolerance due to an acute episode of low back symptoms can be treated similarly during the first month. The goals are to provide patients with accurate information about low back problems, assist with symptom relief, and make appropriate activity recommendations.

Once the history and physical examination are complete, the patient can be assured that there is no hint of a dangerous medical condition causing the back problem and that a rapid recovery is expected. Symptom control methods focus initially on providing the patient with a comfort level adequate to keep the patient as active as possible while awaiting spontaneous recovery. Later in treatment, symptom control is considered an adjunct in helping the patient overcome a specific activity intolerance. The primary methods of symptom control are oral pharmaceuticals and physical methods.

Among the oral medications available to control the discomfort of acute low back problems, the panel recommends acetaminophen as reasonably safe and acceptable. Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, are also acceptable despite the potential for side effects, most frequently gastrointestinal irritation. Muscle relaxants, including benzodiazepines, have been found no more effective than NSAIDs in treating patients with acute low back problems, and potential side effects of these drugs include drowsiness in up to 30 percent of patients. The panel recommended that opioids be avoided if possible because of significant risks of debilitation, drowsiness, decreased reaction time, clouded judgment, and potential misuse. If chosen, they should be used only for a short time. The panel also recommended against the use of oral steroids, colchicine, or antidepressant medications for acute low back problems.

The panel found manipulation to be a recommendable method of symptom control. Manipulation seems helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. If no symptomatic and functional improvement has been noted after 1 month of manipulative therapy, this treatment should be stopped

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and the patient reevaluated. The panel found no evidence of benefit from the application of physical agents and modalities such as ice, heat, massage, traction, ultrasound, cutaneous laser treatment, transcutaneous electrical nerve stimulation (TENS), and biofeedback techniques. Self-application of heat or cold may be taught to patients who choose such options to provide temporary relief of symptoms. Evidence does not support the use of trigger point, ligamentous and facet joint injections, needle acupuncture, or dry needling as treatment for acute low back problems.

The panel found that prolonged bed rest (for more than 4 days) may lead to debilitation and is not appropriate in the treatment of acute low back problems. A gradual return to normal activities is advisable, although bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of sciatica. The patient whose symptoms are aggravated by lifting or prolonged sitting may require specific advice and exploration of alternatives. For most patients, aerobic activities that minimally stress the back (such as walking, biking, or swimming) can be started during the first 2 weeks of acute low back problems. After this, conditioning exercises for trunk muscles (in particular back extensors) may be helpful, especially if the patient's acute low back problems persist, although such exercises may initially aggravate symptoms.

Special Studies and Diagnostic Considerations

The panel recommended that clinicians consider a diagnostic reevaluation that may include special studies if the patient continues to be limited by back symptoms for more than 1 month without improvement. This reevaluation begins with a review and update of the history and physical exam to look again for red flags or evidence of nonspinal conditions causing back symptoms. If none of these is found, an appropriate evaluation can be initiated for either patients with sciatica or those with nonspecific low back symptoms.

For patients limited by sciatica for more than 4 weeks without clear evidence on physical examination of nerve root compromise, electromyography (EMG) and H-reflex tests of the lower limb may provide evidence of suspected neurologic dysfunction. Sensory evoked potentials (SEPs) may be a useful adjunct for assessment of suspected spinal stenosis or spinal cord myelopathy. For patients limited by sciatica for more than 4 weeks with physiologic evidence of neurologic dysfunction, MRI or CT is an appropriate consideration to provide anatomic definition of suspected herniated disc before surgery. Anatomic abnormalities of the lumbar spine (such as degenerative changes or abnormal discs) can be confusing since they increase in frequency as patients age and are often noted on imaging tests in subjects with no symptoms of low back problems. Abnormalities on imaging should corroborate evidence from physical examination or physiologic testing. A referral for surgical consultation is reasonable for

patients with sciatic symptoms who have (1) activity limitations for more than 1 month without improvement, (2) clear clinical or electrophysiological evidence of nerve root compromise, and (3) corroborative findings on imaging studies. Earlier emergency consultation is reserved for patients with findings of bowel and/or bladder dysfunction or progressive and/or severe neurologic impairment. Most patients with symptoms persisting beyond 4 weeks will not be surgical candidates since the majority will have nonspecific acute low back symptoms without evidence of a serious underlying condition.

Following diagnostic or surgical procedures, treatment for those patients who have not recovered focuses on graduated physical conditioning to gain tolerance for activities required at home and/or the workplace. To help patients who have extreme difficulty overcoming their personal activity intolerance, clinicians are encouraged to address any nonphysical factors (such as unrealistic expectations by patient or employer or other psychosocial problems) that can potentially be influenced in a positive manner. The goal is to help the patient recover normal activity tolerance and avoid the development of a chronic low back disability.

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1 Overview

Purpose and Rationale

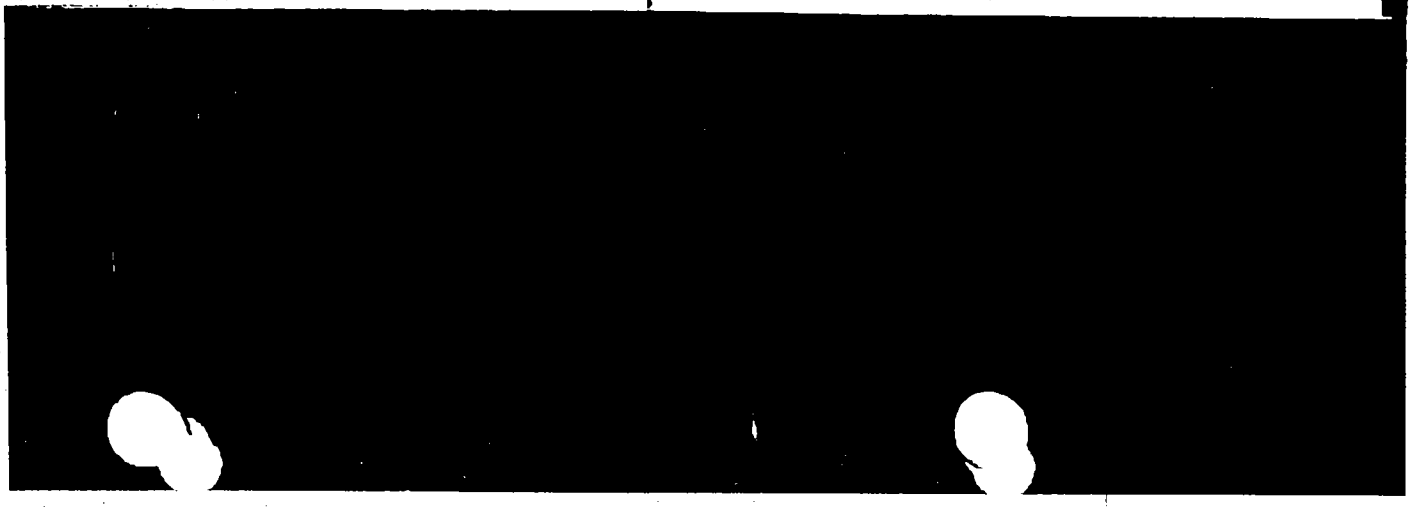
There are four principal reasons acute low back problems were selected as a subject for guideline development. One reason is their prevalence. Most people report low back problems at some time in their lives, and national statistics indicate a general yearly prevalence in the U.S. population of 15–20 percent.[1] Among working-age people surveyed, 50 percent admit to back symptoms each year.[2,3] Back symptoms, in fact, are the most common cause of disability for persons under age 45.[4] At any given time, about 1 percent of the U.S. population is chronically disabled because of back problems, and another 1 percent temporarily disabled.[1]

A second reason for a guideline on assessment and treatment of acute low back problems is cost. Low back problems are expensive. Their total costs to society are difficult to calculate, but evidence indicates that both the economic and psychosocial costs are substantial. Low back problems are the second most common symptomatic reason expressed by patients for office visits to primary care physicians.[5] They are the most common reason for office visits to orthopedic surgeons, neurosurgeons, and occupational medicine physicians. They rank third among the reasons for surgical procedures.

Moreover, although medical costs are high, loss of time from work as well as the disability payments for work-related low back problems can together cost up to three times as much as medical treatment.[6] About 2 percent of the U.S. work force has compensable back problems each year.[7] Various estimates of the total annual societal cost of back pain in the United States range from $20 to $50 billion.[8] Nonmonetary costs of low back problems can also be substantial. The inability to function normally at work and in other daily activities has an impact on both patients and their families.

A third important reason for this guideline is the increasing evidence that many patients with activity intolerance due to low back symptoms may be receiving care that is inappropriate or at least less than optimal. Rates for hospitalization and surgery for low back problems vary substantially among regions of the United States as well as among small areas within states.[9–11] Marked regional variations also occur in the use of diagnostic tests for assessing low back problems.[9] These variations imply a lack of consensus about appropriate assessment and treatment of low back problems, suggesting that some patients may be receiving inappropriate or suboptimal care.

In addition, some patients appear to be more disabled after treatment than before, another potential indicator of suboptimal care. Perhaps the most obvious examples involve surgery. Despite an extensive medical



ture on "failed back surgery" and evidence that repeat surgical dures for low back problems rarely lead to improved outcome, there documented examples of patients who have had as many as 20 spine tions.[1] However, surgery is not the only treatment that can lead to ased disability. Common treatment methods such as extended bed rest tended use of high-dose opioids can prolong symptoms and further litate patients.

A fourth reason for the guideline is a growing body of research on low : problems, allowing a systematic evaluation of commonly used ssment and treatment methods. Although the existing literature has rcomings, there is sufficient scientific evidence for a number of clusions about the efficacy and safety of current assessment and tment methods.

ope and Organization

ope

This *Clinical Practice Guideline* is intended to provide primary care icians with information and recommended strategies for the assessment treatment of acute low back problems in adults. To develop this deline, AHCPR convened a private-sector, multidisciplinary panel of icians, researchers, and a consumer representative to evaluate the ntific evidence in the medical literature, draw conclusions, and make mmendations.

In determining the scope of the guideline, the panel focused on rmation needed for primary care assessment and treatment of adults h acute low back problems. "Back problems" were defined as activity slerance due to back-related symptoms and "acute" as limitations of less n 3 months' duration. Back symptoms include pain in the back as well back-related leg pain (sciatica). The panel agreed that the guideline uld provide information on initial detection of underlying serious nditions (such as fracture, tumor, infection, or cauda equina syndrome) t could be causing low back problems, but that treatment of these nditions is outside the scope of the guideline.

The panel agreed further that the assessment and treatment of patients o have chronic low back problems (with symptoms lasting over months) may be quite different than for patients with acute problems. tients who become disabled due to chronic low back problems represent s than 5 percent of those with low back problems, but they account for to 60 percent of the societal costs for this disorder.[5] To a much greater tent than acute problems, chronic low back problems are influenced by mplex psychological, behavioral, socioeconomic, demographic, legal, and ccupational factors, many of which are not easily controlled.[6] For these asons, the panel decided that chronic low back problems are beyond the ope of a guideline on acute problems. The recommendations included in the guideline may not apply to persons younger than 18 years since diagnostic and treatment considerations for this group are often different than for adults.

Evaluation of Evidence. The panel agreed that this guideline on acute low back problems should be anchored to published scientific evidence, and that such evidence should take priority over panel opinion in making guideline recommendations. In looking at a proposed assessment or treatment method, the panel considered: (1) efficacy, (2) potential harms, and (3) costs.

The panel considered randomized controlled trials (RCTs) that focused on patient-oriented clinical outcome measures such as symptom relief or improved level of functioning to be the acceptable method for establishing the efficacy of treatment methods. Evidence about efficacy of assessment methods was considered adequate if results of the diagnostic test studied were compared to an independent reference standard in a way that allowed calculation of standard test parameters, such as the test's true-positive rate (sensitivity) and true-negative rate (specificity).

The panel agreed to give the greatest weight to scientific research evidence that met the above criteria. When such strong scientific evidence was not available, the panel labeled the evidence as weak and indirect and used the combined expert opinion and clinical judgment of panel members for interpretation. In all cases, the guideline explicitly states the type of evidence used by the panel as the basis for recommendations. The scale used for labeling the evidence is at the end of this chapter.

Prevention Studies. The panel found that, to date, studies of interventions aimed at preventing low back problems or their risk factors present conflicting findings and explain only a small portion of back complaints. Few of these prevention studies have been well designed, and most have been conducted in workplace settings focusing on injury claims or have used interventions that could not easily be carried out by primary care providers. When information from these studies was applicable to primary care, however, it was included under specific areas of assessment or treatment in the guidelines.

The panel agreed that a methodological problem commonly associated with studies of the prevention of back problems is lack of precision in specifying the goal(s) of the preventive intervention. Researchers often fail to establish whether the goal is to prevent the first episode of low back symptoms, activity limitations, recurrent episodes, injury claims, time lost from work, chronic disability, and/or medical care utilization and costs. In addition, some authors have suggested that efforts to prevent first or recurrent episodes of low back symptoms at work may be futile, and that research should focus instead on preventing long-term disability that results in high-cost disability claims.[6,7]

Organization and Clinical Categories

Chapter 2 of this guideline focuses on the initial assessment of the patient with activity limitations due to acute low back symptoms, and Chapter 3 addresses initial treatment methods for these patients. The assessment and treatment methods considered in these chapters can typically be managed by the primary care clinician. Up to 90 percent of patients with acute low back problems recover within 1 month from activity limitations due to symptoms.[4,5,11] Chapter 4 addresses diagnostic and treatment considerations for the small percentage of patients who still have substantial symptoms or limitations after 1 month. Many of these diagnostic and therapeutic methods can be managed by the primary care clinician; others will require consultation with a specialist.

The panel recognized that different clinical disciplines use a variety of diagnostic labels that implicitly suggest a cause for low back symptoms. However, these labels are often unreliable for categorizing causes of acute low back problems. Even after an extensive workup, only about 15 percent of patients can be given a definitive diagnosis.[12]

Since the many diagnostic labels currently used to describe low back problems may confuse patients and clinicians, the panel considered it more useful to classify a patient's acute low back problem into one of three descriptive clinical categories based on medical history and physical examination findings:

- Potentially serious spinal condition: spinal tumor, infection, fracture, or cauda equina syndrome suggested by findings from medical history or physical examination ("red flags").
- Sciatica: back-related lower limb symptoms suggesting nerve root compromise.
- Nonspecific back symptoms: symptoms occurring primarily in the back that suggest neither nerve root compromise nor a serious underlying condition.

In the panel's opinion, clinicians would have enough information to make appropriate decisions about initial assessment and treatment, as well as some hints about prognosis, after correctly classifying patients with low back problems into one of the above three categories. The panel used this classification scheme in making guideline recommendations about assessment and treatment methods.

Methodology for Guideline Development

The general theory and principles underlying development of clinical practice guidelines are presented in an Institute of Medicine report;[13] other reports published by AHCPR provide specific information on the clinical guideline development process.[14] These materials provided a starting point for developing the *Clinical Practice Guideline* on low back problems.

AHCPR provided the general parameters for guideline development. The panel, aided by the methodologist consultants, then independently determined the specific methods for the project, directed the literature review, and developed the guideline findings and recommendations.

Formation of the Panel and Staff

AHCPR initiated formation of the panel and appointed its chairperson and members. Important considerations in the choice of panel members were: (1) demonstrated knowledge about low back problems, (2) representation of major clinical disciplines involved in back care, and (3) geographic diversity. Nominations were solicited through a *Federal Register* announcement and from professional and consumer organizations and persons interested in the care of patients with low back problems.

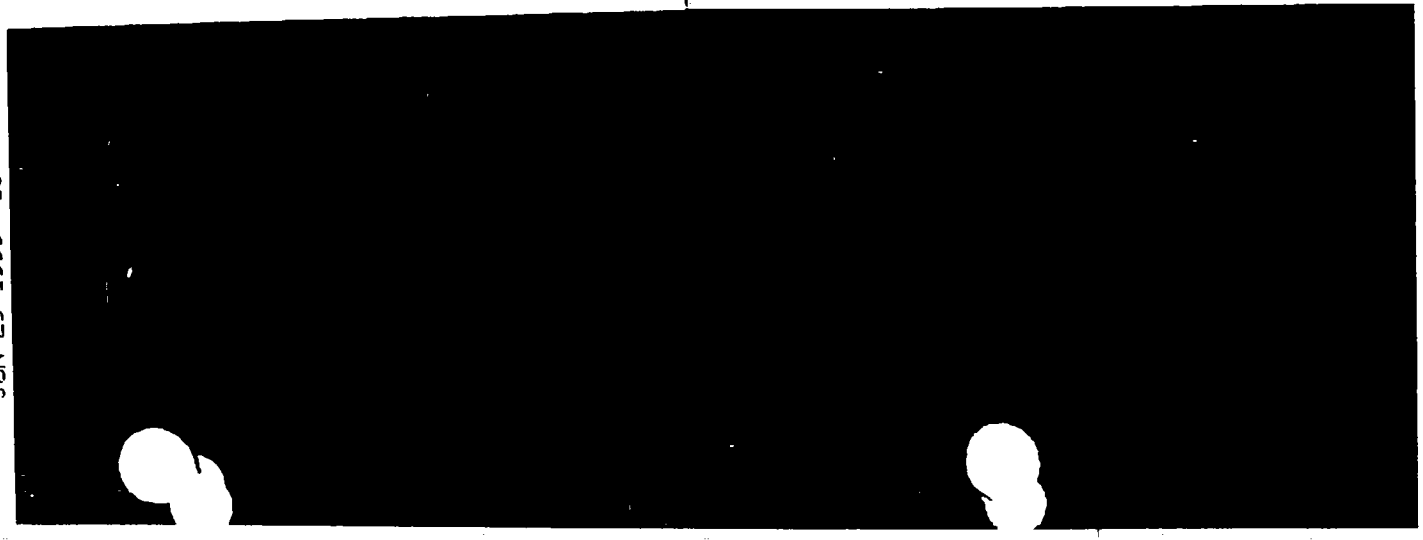
More than 200 individuals were nominated. AHCPR selected 23 representing the fields of biomechanical and spine research, chiropractic care, emergency medicine, family medicine, internal medicine, neurology, neurosurgery, occupational health nursing, occupational medicine, occupational therapy, orthopedics, osteopathic medicine, physical and rehabilitation medicine, physical therapy, psychology, rheumatology, and radiology.

The panel also included a consumer representative who had experienced low back problems, but did not work in the health care field. Several consultants with expertise in spine research, clinical care of low back problems, clinical epidemiology, and health economics were appointed to the panel. Two methodologists with experience in developing clinical practice guidelines were assigned to the panel by AHCPR. Both methodologists were physicians with MPH degrees, one an emergency medicine physician and one an internist. The methodologists aided the panel in determining the scope of the literature search and the criteria to be used for selecting articles for panel review.

The panel chair formed a research and support staff that included two physicians: a spine-fellowship-trained orthopedic surgeon and an occupational-medicine-trained physician with an MPH degree. National Library of Medicine representatives aided the staff in retrieving literature. The staff screened articles and constructed evidence tables for articles according to panel review criteria. These evidence tables and the original articles were presented to the panel for review and interpretation. The panel used this information as the basis for its guideline findings and recommendations.

Public Comment and Peer Review

An open forum was held early in the guideline development process to give interested individuals, organizations, and agencies the opportunity to present written or verbal testimony. Later in the process, drafts of the



guideline were sent out for peer and pilot review. AHCPR selected peer and pilot reviewers from those who had expressed interest in the guideline, participated in the open forum, or were nominated by professional organizations or panel members.

Over 100 peer reviewers were selected based on their expertise in the care of low back problems. They were asked to evaluate the comprehensiveness of the literature review as well as the panel's findings and recommendations. The pilot reviewers who were selected represented a cross-section of primary care settings including private and group practices, health maintenance organizations, and occupational medicine clinics. They were asked to evaluate the practical applicability of the guideline in their own practice settings by using examples published in the *Quick Reference Guide for Clinicians* and by soliciting feedback from patients given the *Consumer Version*. The panel used comments from peer and pilot reviewers to guide final revisions of the guideline.

Literature Search

The panel initiated a comprehensive literature search of topics deemed applicable to low back problems. The Quebec Task Force on Spinal Disorders had previously published an evidence-based guideline on low back problems, based upon an exhaustive literature search through 1984.[15] The bibliography from their report was the starting point in the literature search for this AHCPR guideline.

The literature search of articles published after 1984 was performed through the National Library of Medicine. Abstracts of 10,317 articles which met the search criteria were each independently evaluated by the orthopaedic surgeon and occupational medicine physician on the research staff. If either reviewer thought an article might be useful, the entire article was retrieved. A total of 3,918 articles (38 percent of all abstracts evaluated) was obtained for further evaluation.

Additional articles came from panel members, from the open forum process, and from unsolicited sources. All articles were entered in a comprehensive bibliography, classified by topic, and screened methodologically to determine if they contained information that might be useful to the panel.

Evaluation of Efficacy

In evaluating efficacy of assessment and treatment methods, the panel decided to focus on how each method affected clinical outcomes important to patients and society. Examples of such outcomes are symptoms, level of physical functioning, patient satisfaction, and morbidity and mortality (as complications of the assessment or treatment method). The panel dealt with costs, another outcome of interest to patients and society, as a separate issue. Cost was not considered when evaluating efficacy.

The panel used a standard methodology to identify and evaluate the best scientific evidence available on the efficacy of each assessment and treatment method, while focusing on clinical outcomes. This process included a systematic evaluation of each study's quality and its clinical applicability to patients with acute low back problems. The panel used this information to screen all articles, using minimum article selection criteria for efficacy. Articles meeting these minimum criteria were prioritized (giving priority to articles of higher quality and clinical applicability), and data from the higher priority articles were abstracted onto evidence tables.

The panel then reviewed the available data from both evidence tables and original articles to decide how much weight to give each study in developing the "findings and recommendations" statements for this guideline. The greatest weight was given to studies of high quality that evaluated adults with acute low back problems, although few such studies were found.

For most topics, the quality and clinical applicability of studies reviewed were limited. Inclusion and exclusion criteria for subjects were often either incompletely described or so broad that they allowed for wide variations in age, symptoms, symptom duration, examination findings, prior treatments, and other potentially confounding factors. Studies often inadequately described the baseline demographic and clinical characteristics of subjects. Many studies did not distinguish acute from chronic patients; others failed to either describe or control for factors known to cause significant variation in outcome (such as prior back surgery). Certain studies lacked appropriate statistical analysis or included too few subjects to attain adequate statistical power.

Evaluation of Potential Harms and Costs

Evaluating Harms. Since back problems are rarely life-threatening, the panel paid special attention to potential harms (side effects or complications) of assessment and treatment methods. Controlled trials evaluating treatment and assessment methods, however, seldom included enough subjects to detect rare but potentially serious complications. This information was found only in large case series or case reports. On the other hand, controlled trials of oral medications often included extensive information on side effects. Thus, accurate comparison of the relative risks of side effects and complications of different assessment and treatment methods was not possible.

A lack of published evidence about harms related to specific treatment or assessment methods does not mean that potential harms do not exist. In many instances, the side effects and complications of assessment and treatment methods have never been extensively studied or comprehensively reported. In addition, articles evaluating newer treatment and assessment methods are often written by advocates of these methods, who may tend to deemphasize the harms.

The panel felt it wa tant for both clinicians and patients to have sense of potential harm ive to the potential benefits of these ethods. Therefore, the panel considered information about potential rms from a variety of sources, including case series, case reports, cross-ctional surveys, clinical trials, and in some instances studies of patients ho did not have low back problems. Finally, if no specific information as available from any of these sources, the panel generally considered hether the method was invasive or carried the potential for an allergic action.

Evaluating Costs. Both clinicians and patients need to consider lative costs of assessment and treatment methods before making formed decisions about care. Costs vary greatly, however, and the cost ta on assessment and treatment methods for low back problems are nited. The unit cost of a service may vary within and between ographical regions. The aggregate cost of services also varies depending the frequency and duration of services for the individual patient. lthough costs of various medical services have generally increased in cent years, they have done so at inconsistent rates. Given these riations, the panel decided to make broad statements about whether ethods appeared to be of low, moderate, or high cost, graded according the following system (based on 1993 dollars):

Low cost: under $200.
Moderate cost: $200 to $1,000.
High cost: over $1,000.

This grading system provides no more than a rough comparison of sts, and the panel recognized that the divisions between cost categories e somewhat arbitrary. For example, some Americans may not consider a 199 expense that comes directly out of pocket to be "low cost."

eveloping the Guideline Recommendations

To develop recommendations for each assessment and treatment ethod, the panel considered: (1) the quality and amount of evidence for ficacy, (2) the strength of the effect found for the method, (3) the nsistency of findings between studies, (4) the clinical applicability of the idence to adult patients with acute low back problems, and (5) any idence on harms or costs. For each assessment and treatment method the nel then sought to answer the following questions:

What is the likelihood that this assessment or treatment method will:
- Benefit the patient?
- Harm the patient?

Does the likelihood and magnitude of potential benefit outweigh the likelihood and magnitude of potential harm enough to justify the cost for this method?

The development of "findings commendations" statements required the collective judgment c nel in interpreting the available evidence. The panel rated the amo. od quality of evidence supporting each guideline statement using the scale in Figure 1 below.

Figure 1. Panel ratings of available evidence supporting guideline statements

A = Strong research-based evidence (multiple relevant and high-quality scientific studies).

B = Moderate research-based evidence (one relevant, high-quality scientific study or multiple adequate scientific studies*).

C = Limited research-based evidence (at least one adequate scientific study* in patients with low back pain).

D = Panel interpretation of information that did not meet inclusion criteria as research-based evidence.

*Met minimal formal criteria for scientific methodology and relevance to population and specific method addressed in guideline statement.

This rating system (A, B, C, or D) is the basis for:

Recommendations for: If the available evidence indicates that potential benefits outweigh potential harms.

Options: If the available evidence of potential benefits is weak or equivocal (inconsistency in some studies) but potential harms and costs appear small.

Recommendations against: If the available evidence indicates either a lack of benefit or that potential harms and costs outweigh potential benefits.

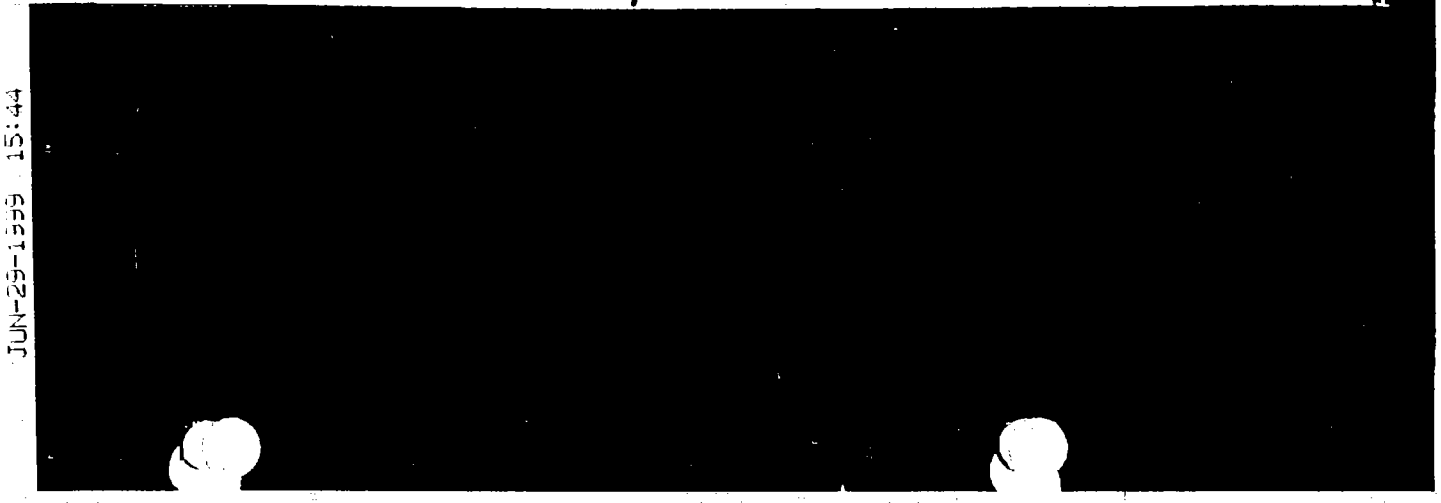
The guideline's findings and recommendations statements therefore represent the panel's assessment of a method's potential to achieve the intended assessment or treatment goals, balanced against its potential harms and costs.

2 Initial Assessment Methods

Panel findings and recommendations:

- Information about the patient's age, the duration and description of symptoms, the impact of symptoms on activity, and the response to previous therapy are important in the care of back problems. (Strength of Evidence = B.)
- Inquiries about history of cancer, unexplained weight loss, immunosuppression, intravenous drug use, history of urinary infection, pain increased by rest, and presence of fever are recommended to elicit red flags for possible cancer or infection. Such inquiries are especially important in patients over age 50. (Strength of Evidence = B.)
- Inquiries about signs and symptoms of cauda equina syndrome, such as a bladder dysfunction and saddle anesthesia in addition to major limb motor weakness, are recommended to elicit red flags for severe neurologic risk to the patient. (Strength of Evidence = C.)
- Inquiries about history of significant trauma relative to age (for example, a fall from height or motor vehicle accident in a young adult or a minor fall or heavy lift in a potentially osteoporotic or older patient) are recommended to avoid delays in diagnosing fracture. (Strength of Evidence = C.)
- Attention to psychological and socioeconomic problems in the individual's life is recommended since such nonphysical factors can complicate both assessment and treatment. (Strength of Evidence = C.)
- Use of instruments such as a pain drawing or visual analog scale is an option to augment the history. (Strength of Evidence = D.)
- Recording the results of straight leg raising (SLR) is recommended in the assessment of sciatica in young adults. In older patients with spinal stenosis, SLR may be normal. (Strength of Evidence = B.)
- A neurologic examination emphasizing ankle and knee reflexes, ankle and great toe dorsiflexion strength, and distribution of sensory complaints is recommended to document the presence of neurologic deficits. (Strength of Evidence = B.)

The initial assessment (Attachment A1) of a patient with activity intolerance due to acute low back symptoms consists of a focused medical history, a physical examination, and related decisions. A careful medical history and physical examination are critical. The primary purpose is to seek medical history responses or physical examination findings suggesting a serious underlying condition such as fracture, tumor, infection, or cauda equina syndrome. These responses or findings are referred to as red flags. They alert clinicians to the possibility that low back symptoms may be



related to a danger[illegible]ondition. However, serious conditions presenting as low back problem[illegible]latively rare.

The initial asse[illegible]ent categorizes back symptoms without red flags as either primarily back (nonneurologic) or sciatic (neurologic) and defines the duration of these symptoms to guide both what type of special studies may be considered and when they should be considered. In the absence of red flags, special tests are not usually required in the first month of low back symptoms because most patients recover from their activity limitations within 1 month.

The initial assessment also provides an opportunity for the clinician to establish rapport with the patient, to find out patient expectations, and to become aware of potential psychological and socioeconomic factors that can alter response to care.

Assessment Literature Reviewed

Of the 214 articles screened for this topic, 34 met the article selection criteria for efficacy.[20-53]

The important points in these articles are well summarized in review articles by Deyo, Rainville, and Kent[54] and Waddell, Main, Morris, et al.[13] Both reviews elaborate on the reproducibility and accuracy of specific medical history findings (Table 1) and physical examination findings (Table 2) for assessing low back problems. Other articles not meeting selection criteria are cited where appropriate since they contain information used in formulating recommendations.[20-45]

Evidence on Efficacy of Assessment Methods

Medical History

A few key questions on the medical history can help ensure that a serious underlying condition, such as cancer[20] or spinal infection, will not be missed. These questions include: age, history of cancer, unexplained weight loss, immunosuppression, duration of symptoms, responsiveness to previous therapy, pain that is worse at rest, history of intravenous drug use, and urinary or other infection.

Symptoms of sciatica (leg pain) or neurogenic claudication (walking limitations due to leg pain) suggest possible neurologic involvement. Pain radiating below the knee is more likely to indicate a true radiculopathy than pain radiating only to the posterior thigh. A history of persistent numbness or weakness in the leg(s) further increases the likelihood of neurologic involvement. The articles indicate that cauda equina syndrome can be ruled out with a medical history that ascertains the absence of bladder dysfunction (usually urinary retention or overflow incontinence), saddle anesthesia, and unilateral or bilateral leg pain and weakness.

Table 1. Estimated accuracy [illegible]dical history in diagnosis of spine diseases causing low back [illegible]ns

References[a]	Disease(s) the test is directed to	Medical history finding/"red flag"	True-positive rate (sensitivity)	True-negative rate (specificity)
Deyo and Diehl[55]	Cancer	Age ≥50	0.77	0.71
		Previous cancer history	0.31	0.98
		Unexplained weight loss	0.15	0.94
		Failure to improve with 1 month of therapy	0.31	0.90
		Bed rest no relief	>0.90	0.48
		Duration of pain >1 month	0.50	0.81
		Age ≥50 or history of cancer or unexplained weight loss or failure of conservative therapy	1.00	0.60
Waldvogel and Vasey[56]	Spinal osteomyelitis	Intravenous drug abuse, UTI, or skin infection	0.40	NA
Unpublished data[a]	Compression fracture	Age ≥50	0.84	0.61
		Age ≥70	0.22	0.96
		Trauma	0.30	0.85
		Corticosteroid use	0.08	0.995
Deyo and Tsui-Wu[58], Spangfort[59]	Herniated disc	Sciatica	0.95	0.59
Turner, Ersek, Herron, et al.[60]	Spinal stenosis	Pseudoclaudication	0.60	NA
		Age ≥50	0.90[b]	0.70
Gran[61]	Ankylosing spondylitis	Positive response 4 out of 5	0.23	0.82
		Age at onset ≤40	1.00	0.07
		Pain not relieved in supine position	0.80	0.48
		Morning back stiffness	0.84	0.59
		Duration of pain ≥3 months	0.71	0.64

[a] From 833 patients with back pain at a walk-in clinic as reported in Deyo, Rainville, and Kent.[54] All received plain lumbar roentgenograms.
[b] Author's estimate.

Table 2. Estimated accuracy of physical examination for lumbar disc herniation among patients with sciatica

References	Test	True-positive rate (sensitivity)	True-negative rate (specificity)	Comments
Hakelius and Hindmarsh[91]; Kosteljanetz, Espersen, Halaburt, et al.[37]	Ipsilateral SLR	0.80	0.40	Positive result: leg pain at <60°
Hakelius and Hindmarsh[91]; Spangfort[59]	Crossed SLR	0.25	0.90	Positive result: reproduction of contralateral pain
Hakelius and Hindmarsh[91]; Spangfort[59]	Ankle dorsiflexion weakness	0.35	0.70	HNP usually at L4-L5 (80%)
Hakelius and Hindmarsh[91]; Kortelainen, Puranen, Koivisto, et al.[33]	Great toe extensor weakness	0.50	0.70	HNP usually at L5-S1 (60%) or L4-L5 (30%)
Hakelius and Hindmarsh[91]; Spangfort[59]	Impaired ankle reflex	0.50	0.60	HNP usually at L5-S1; absent reflex increases specificity
Kortelainen, Puranen, Koivisto, et al.[33]; Kosteljanetz, Espersen, Halaburt, et al.[37]	Sensory loss	0.50	0.50	Area of loss poor predictor of HNP level
Aronson and Dunsmore[16]	Patellar reflex	0.50	NA	For upper lumbar HNP only
Hakelius and Hindmarsh[91]	Ankle plantar flexion weakness	0.06	0.95	—
Hakelius and Hindmarsh[91]	Quadriceps weakness	<0.01	0.99	—

Note: Sensitivity and specificity were calculated by Deyo, Rainville, and Kent.[34] Values represent rounded averages where multiple references were available. All results are from surgical case series. HNP = herniated nucleus pulposus. SLR = straight leg raising.

Patients' reports of symptoms and treatment outcomes may be influenced by psychological or socioeconomic factors. Several studies have reported a variety of such factors for patients with low back problems. These factors include work status, typical job tasks, educational level, pending litigation, worker's compensation or disability issues, failed previous treatments, substance abuse, and depression.[illegible]

Clinicians are urged by some authors to augment the medical history with pain drawings and visual analog pain rating scales to document the distribution of pain and intensity of symptoms (Attachment B).[illegible]

Physical Examination

The physical examination supplements the information obtained in the medical history in seeking an underlying serious condition or possible neurologic compromise. The basic elements of a physical examination are inspection, palpation, observation including range of motion testing, and a specialized neuromuscular evaluation. This evaluation emphasizes ankle and knee reflexes, ankle and great toe dorsiflexion strength, and distribution of sensory complaints. For patients presenting with acute low back problems and no limb complaints, a more elaborate neurologic evaluation is usually not necessary.

The physical examination is less useful than the history in searching for underlying serious conditions such as cancer, but may be helpful in detecting spinal infections. Fever, vertebral tenderness, and very limited spinal range of motion suggest the possibility of spinal infections, but these are also common findings in patients without infection. Otherwise, evaluation of spinal range of motion has been found to be of limited diagnostic value,[60] although some clinicians consider it helpful in planning and monitoring treatment.

Findings from both the history and physical examination provide useful information in the search for possible neurologic compromise. For example, sciatica has such a high true-positive rate for lumbar nerve root compression that its absence makes a clinically important lumbar disc herniation related to neural compression unlikely. In addition, leg pain usually overshadows back pain when such a clinically significant radiculopathy is present. Finally, crossed straight leg raising is such a highly specific test that a positive finding makes neurologic compromise due to herniated lumbar disc very likely, but this is not a sensitive test since discomfort upon crossed straight leg raising may be absent in many patients with neurologic compression.[illegible]

Deyo, Rainville, and Kent's summary[34] of available data suggests that in the primary care setting for patients with leg symptoms, the neurologic examination can safely be limited to a few tests. These are: (1) testing of dorsiflexion strength of the ankle and the great toe, with weakness suggesting L5 and some L4 root dysfunction; (2) testing of ankle reflexes to evaluate S1 root dysfunction; (3) testing of light touch sensation in the

medial (L4), dorsal (L5) and lateral (S1) aspects of the foot; and (4) the straight leg raising test.

This abbreviated neurologic examination of the lower extremities will allow detection of most clinically significant nerve root compromise due to L4-L5 or L5-S1 disc herniations, which together make up over 90 percent of all clinically significant radiculopathy due to lumbar disc herniations.[30,31,32] Although this limited examination might miss the much less common L2-L3 or L3-L4 disc herniations, these conditions are more difficult to diagnose on physical examination. Moreover, if such patients have not improved by 1 month, this guideline suggests a further diagnostic workup or consultation (Chapter 4), which may clarify the diagnosis. For over 95 percent of patients with acute low back problems, no special interventions or diagnostic tests would be required within the first month of symptoms.

Potential Harms and Costs of Assessment Methods

Potential harms and costs are considered low for both the medical history and the physical examination.

Summary of Findings

Positive answers to key medical history questions, in addition to positive findings on physical examination and/or simple lab tests, are red flags that suggest the possibility of a serious underlying condition as the cause of acute low back problems.

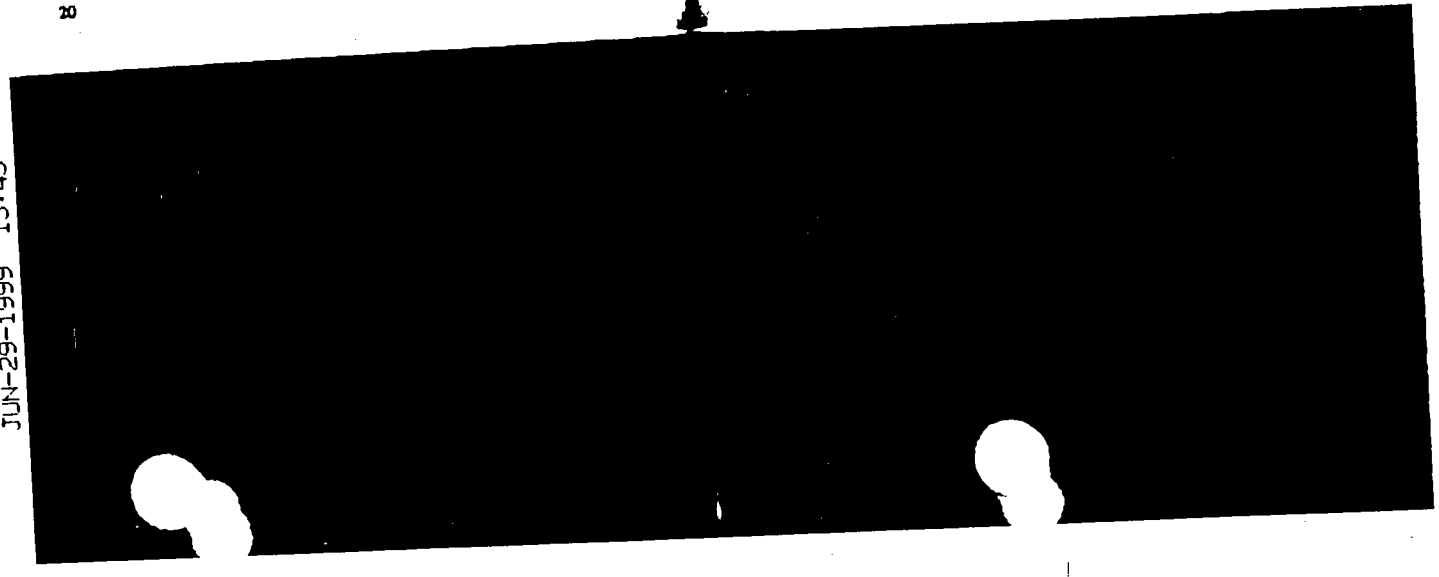
For cancer or infection, red flags are: history of cancer, unexplained weight loss, immunosuppression, urinary infection, intravenous drug use, prolonged use of corticosteroids, back pain not improved with rest, and age of patient over 50.

For spinal fracture, red flags are: history of significant trauma (for example, a fall from a height, motor vehicle accident, or direct blow to the back for a young adult, or a minor fall or heavy lift in a potentially osteoporotic or elderly individual), prolonged use of steroids, and age over 70.

For cauda equina syndrome or severe neurologic compromise, red flags are: medical history or physical examination findings of acute onset of urinary retention or overflow incontinence, loss of anal sphincter tone or fecal incontinence, saddle anesthesia (about the anus, perineum, and genitals), and global or progressive motor weakness in the lower limbs.

There are indications in the literature that psychological or socioeconomic factors may affect a patient's report of symptoms and response to treatment.

Simple laboratory tests, including the erythrocyte sedimentation rate (ESR), are sufficiently inexpensive and efficacious for use as initial tests when there is suspicion of back-related tumor or infection.



3 Clinical Care Methods

In the absence of red flags, treatment is similar for most patients with activity intolerance due to an acute episode of low back symptoms (Attachment A2). After assuring the patient that there is no hint of a dangerous problem and that a rapid recovery is expected, the goals are to provide accurate patient information about low back problems, to help provide comfort by means of symptom control methods, and to recommend activity modifications.

Patient Information

Patient Education About Low Back Symptoms

Panel findings and recommendations:

Patients with acute low back problems should be given accurate information about the following (Strength of Evidence = B):

- Expectations for both rapid recovery and recurrence of symptoms based on natural history of low back symptoms.
- Safe and effective methods of symptom control.
- Safe and reasonable activity modifications.
- Best means of limiting recurrent low back problems.
- The lack of need for special investigations unless red flags are present.
- Effectiveness and risks of commonly available diagnostic and further treatment measures to be considered should symptoms persist.

Patient education as defined here includes all forms of patient-oriented education about low back problems except for "back schools" (formally structured, classroom-style back education programs). Under this definition, patient education includes printed and audiovisual materials, information given by health care providers, and educational programs that are less formal than back schools.

Literature Reviewed. Of 14 articles screened for this topic, 2 met the criteria for review.[67,68] Other articles contained information used by the panel, but did not meet article selection criteria.[69-71]

Neither of the studies meeting the criteria focused solely on patients with acute low back problems. Both evaluated patients with low back problems of unspecified duration. Interventions evaluated included giving patients booklets on back pain[68] and holding a brief individual educational session during an emergency room visit or by phone after the visit.[67]

Evidence on Efficacy. Jones, Jones, and Katz[67] evaluated educational intervention for patients with low back problems who came to a hospital emergency department and were referred for followup care. Patients

receiving an educational intervention in the emergency department and/or a followup phone c[illegible] more likely than control patients to schedule and keep their followu[illegible] [illegible]ntment.

Roland and Dixon[illegible] conducted a randomized controlled trial (RCT) in which patients presenting with low back problems were assigned either to a group receiving an educational booklet on back problems or to a control group receiving no educational materials. In the first 2 weeks after the intervention, no differences were found between the education and control groups in number of consultations for back pain. However, in the period from 2 weeks to 1 year after the intervention, significantly fewer patients in the group receiving the booklet consulted physicians for back pain.

The importance of providing information to the patient is indicated in a study by Deyo and Diehl.[illegible] Failure to receive an explanation of the problem was the most frequently cited source of patient dissatisfaction among 140 patients with low back problems. Patients who felt they did not receive an adequate explanation wanted more diagnostic tests, were less satisfied with their visit, and were less likely to want the same doctor again, compared with patients who reported an adequate explanation.

Thomas[illegible] randomly assigned patients with symptoms (including low back pain), but no definite diagnosis, to one of four consultations: either one of two positive consultations, with and without treatment, or one of two negative consultations, with and without treatment. In the positive consultations, patients were given a firm diagnosis and told confidently that they would be better in a few days. The negative consultations were devised so that no firm assurance was given. Two weeks later the difference in recovery was significant between the positive and negative groups, but not between the treated and untreated groups.

A study of patients visiting family physicians for common symptoms, including back or neck pain, found that gaining patient agreement about the nature of the problem led to earlier resolution.[illegible]

Potential Harms and Costs. The potential risks, harms, and costs of educating patients are considered to be low.

Summary of Findings. Evidence indicates that educating patients about back problems may reduce use of medical resources, decrease patient apprehension, and speed recovery.

Structured Patient Education: Back School

Panel findings and recommendations:

- In the workplace, back schools with worksite-specific education may be effective adjuncts to individual education efforts by the clinician in the treatment of patients with acute low back problems. (Strength of Evidence = C.)
- The efficacy of back schools in nonoccupational settings has yet to be demonstrated. (Strength of Evidence = C.)

"Back school" is defined here as a structured program of education about low back problems, usual[illegible] a group setting. The therapeutic objectives are to give the pati[illegible] [illegible]mation on the anatomy and natural history of disorders of the back, [illegible]ach the principles underlying posture, daily activities, and sports; and thereby to increase functional work capacity.

Literature Reviewed. Of 35 articles screened for this topic, 15 reporting on 12 RCTs met criteria for review.[illegible]

Two meta-analyses regarding back schools were also examined.[illegible] The panel used information from one other study that did not meet selection criteria.[illegible]

Evidence on Efficacy. One of the few studies demonstrating the efficacy of back school[illegible] was conducted in the medical department of a Swedish automotive assembly plant. The 217 subjects all had nonspecific low back pain for less than 3 months and were randomly assigned to one of three interventions: back school, combined physiotherapy exercise, or placebo shortwave diathermy. The back school intervention consisted of four 45-minute sessions in 2 weeks and included the following topics: anatomy and causes of low back problems, muscle function and posture, ergonomics, and advice on physical activity. Patients attending back school had a shorter duration of sick leave during the initial episode than the other two treatment groups, but at the 1-year followup neither the number nor the length of absences from work owing to recurrences differed among the three treatment groups.

A meta-analysis by Keijsers, Bouter, and Meertens[illegible] evaluated eight studies of back schools done in group settings.[illegible] These studies of back schools were compared in terms of program duration and content, patient selection criteria, number of patients, interventions, and outcome measures used. All eight studies were found to have major methodological problems. The authors found that although there was insufficient evidence to form a strong and valid judgment on the efficacy of back schools, the available evidence suggested that back schools are at most marginally effective.

Another meta-analysis by Linton and Kamwendo[illegible] reviewed the scientific literature on back schools and reported some positive effects in studies of patients with acute back pain. However, the authors found that most studies of back schools lacked adequate control groups and that the evidence on efficacy is inconclusive.

Potential Harms and Costs. The potential risks and harms of back schools are considered low. Costs are variable, depending on the number of sessions and the setting, and range from moderately inexpensive to expensive.

Summary of Findings. Available data on formal patient education programs, or back schools, vary in terms of program quality, length, content, costs, and outcomes. Only one study of a structured low back

education program, performed in industry, was found to have a positive short-term impact on acute low back problems although no effect was seen at 1-year followup.[38] In summary, the published evidence on back school as a treatment for acute low back problems is limited in quantity and the results are contradictory.

Symptom Control Methods

Symptom control methods focus initially on providing comfort to keep the patient as active as possible while awaiting spontaneous recovery and, later in treatment, on aiding the activation needed to overcome a specific activity intolerance. The methods traditionally include oral medications, such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), as well as physical treatments. They also include therapeutic injections. Proving the efficacy of these methods to relieve acute low back symptoms is difficult due to the rapid rate of spontaneous recovery. The use of symptom control methods known to have less risk of harm than methods with proven efficacy may thus be warranted if such methods are inexpensive and allow an individual to remain active or build activity tolerance through exercise.

Symptom Control: Medications

Acetaminophen and NSAIDs

Panel findings and recommendations:

- Acetaminophen is reasonably safe and is acceptable for treating patients with acute low back problems. (Strength of Evidence = C.)
- Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, are acceptable for treating patients with acute low back problems. (Strength of Evidence = B.)
- NSAIDs have a number of potential side effects. The most frequent complication is gastrointestinal irritation. The decision to use these medications can be guided by comorbidity, side effects, cost, and patient and provider preference. (Strength of Evidence = C.)
- Phenylbutazone is not recommended, based on an increased risk for bone marrow suppression. (Strength of Evidence = C.)

Acetaminophen, a nonnarcotic analgesic, has commonly been regarded as having an analgesic effect, but little or no known anti-inflammatory mechanism. The therapeutic objective for its use in acute low back problems is pain relief.

NSAIDs are a class of medications, including aspirin, ibuprofen, indomethacin, phenylbutazone, and a variety of other drugs. They have anti-inflammatory and analgesic properties as well as being prostaglandin inhibitors. The therapeutic objective of NSAIDs in treating acute low back problems is to decrease pain, presumably by [illegible] promoting healing.

Literature Reviewed. Of 50 articles screened for this topic, 4 RCTs met the review criteria for adequate evidence about efficacy.[4,39-41] Other articles did not meet the criteria, but contained information used by the panel.[10-12]

Evidence on Efficacy. The four RCTs that met review criteria for this topic were all double-blind studies comparing NSAIDs with a placebo in treating patients with low back problems. No studies were found that compared acetaminophen to placebo in treatment of patients with low back pain.

Two studies compared a single NSAID to a placebo: Amlie, Weber, and Holme[39] evaluated piroxicam. Postacchini, Facchini, and Pallieri[40] evaluated diclofenac. The study by Berry, Bloom, Hamilton, et al.[41] had three treatment groups evaluating either one of two NSAIDs (diflunisal or naproxen sodium) or a placebo. The study by Basmajian[41] compared four treatment groups receiving an NSAID alone (diflunisal), a muscle relaxant alone (cyclobenzaprine), the two in combination, or a placebo.

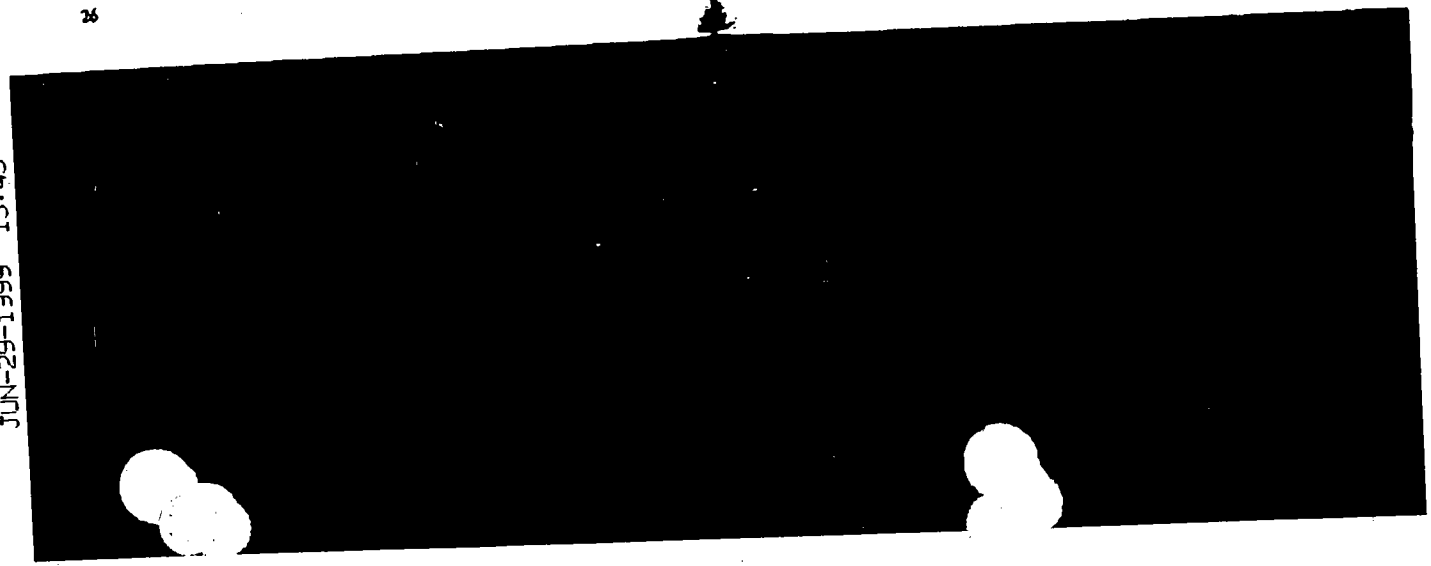
Three of the studies evaluated patients with acute low back symptoms of less than 3 months' duration.[4,39,41] Berry, Bloom, Hamilton, et al.[41] evaluated patients with chronic low back pain.

Three studies found NSAIDs superior to a placebo for pain relief in the short term: from 1 week to 2 months of symptom duration.[4,39,40] The remaining study found no significant difference between NSAID and placebo in terms of pain improvement scores.[41]

Although there were no RCTs comparing acetaminophen to placebo for patients with low back pain, one nonplacebo-controlled RCT found an NSAID (diflunisal) superior to paracetamol (which is similar to acetaminophen) in producing pain relief for patients with chronic low back pain.[42] In addition, the literature on acetaminophen does show it to be more effective than placebo in studies of patients with nonback-related pain.[43,44]

Several RCTs comparing efficacy of different NSAIDs in the same study have found no NSAID to be consistently more effective than the others.[4,41,45] However, these studies also suggest that individual patients report better pain relief from some NSAIDs compared with others. For this reason, Brooks and Day[42] suggest that patients change to a different NSAID if no relief is reported after a 2-week trial.

Potential Harms and Costs. The risks from the use of acetaminophen at usual doses are low.[46] However, high doses of acetaminophen can lead to liver damage, and massive single doses sometimes lead to fatal hepatic necrosis. Compared with NSAIDs, acetaminophen has a minimal effect on platelets and few gastrointestinal side effects since it is not a mucosal irritant. Acetaminophen is inexpensive. The expense of treatment with NSAIDs varies greatly, depending on the medication used and the length of treatment.



Potential complications of NSAIDs have been extensively studied.[93,95] These include gastric and other gastrointestinal complaints, including bleeding in 20 to 30 percent of those patients with active peptic ulcer problems. The degree of gastrointestinal side effects from NSAIDs appears to be dose related, but side effects can occur with one tablet. Ingestion of NSAIDs with meals or in combination with antacids has not been proven effective in reducing these gastrointestinal side effects. However, one medication (misoprostol), when taken with NSAIDs, has been shown to reduce NSAID-induced gastric erosion and the risk for gastroduodenal ulcers.[95,120]

NSAIDs interfere with platelet adhesion and renal sodium metabolism. Their use in patients with a bleeding diathesis is considered contraindicated. They can be used in the presence of hypertension, renal disease, and edematous states, but only if great caution is exercised.[93] For these reasons, some experts caution that routine blood tests (such as CBC and serum chemistry screen) be done before treatment for older patients or those with vascular disease. These tests are also recommended if there is any suspicion of complications for those patients on prolonged NSAID therapy.[93]

Phenylbutazone has been associated with bone marrow suppression (aplastic anemia and agranulocytosis). Indomethacin has a higher reported incidence of gastrointestinal side effects than other NSAIDs. Otherwise, there is no significant demonstrated difference between remaining NSAID preparations in terms of the prevalence or severity of complications.[93]

Summary of Findings. There is fair to good evidence that NSAIDs are effective for reducing pain in patients with acute low back problems. Although no studies were found comparing acetaminophen to placebo in patients with back pain, there is evidence that acetaminophen is comparable in efficacy to NSAIDs for treating back problems and with fewer side effects. In studies of patients with nonback pain, no consistent difference in symptom relief has been demonstrated between acetaminophen and any available NSAID (including aspirin). Both NSAIDs and acetaminophen have been found to be generally adequate to achieve pain relief.

Muscle Relaxants

Panel findings and recommendations:

- Muscle relaxants are an option in the treatment of patients with acute low back problems. While probably more effective than placebo, muscle relaxants have not been shown to be more effective than NSAIDs. (Strength of Evidence = C.)
- No additional benefit is gained by using muscle relaxants in combination with NSAIDs over using NSAIDs alone. (Strength of Evidence = C.)

- Muscle relaxants have potential side effects, including drowsiness in up to 30 percent of patients. When considering the optional use of muscle relaxants, the clinician should balance the potential for drowsiness against a patient's intolerance of other agents. (Strength of Evidence = C.)

Muscle relaxants are commonly used for the treatment of low back problems. Pharmacologically, these are usually benzodiazepines, other sedative medications, or antihistamine derivatives. The therapeutic objective of muscle relaxants is to reduce low back pain by relieving muscle spasm. However, the concept of skeletal muscle spasm is not universally accepted as a cause of symptoms, and the most commonly used muscle relaxants have no peripheral effect on muscle spasm.

Literature Reviewed. Of 42 articles screened for this topic, 12 RCTs met review criteria for adequate evidence about efficacy.[91,105-116]

Evidence on Efficacy. Three studies evaluating patients with low back problems either did not specify duration of symptoms or included a mix of patients with acute and chronic problems.[106,113,116] The remaining nine studies evaluated only patients with acute low back problems.

Of the articles that met review criteria, 9 evaluated a muscle relaxant compared with a placebo.[91,105,106,108-110,112,113] Two studies compared two different muscle relaxants.[107,114] Some of the studies also compared a muscle relaxant to another medication, including a barbiturate;[111,115] an NSAID;[111,116] and acetaminophen.[91]

Of the nine studies comparing muscle relaxants with placebos, seven had results favoring the muscle relaxant.[105,106,108-111,113] Two showed no difference in outcomes between muscle relaxant and placebo.[91,112] In most studies, the positive effect for muscle relaxants was short-lived, lasting no more than 4 to 7 days, with no significant difference from placebo seen after this time.

Panel methodologists did a meta-analysis of the 12 studies that met panel review criteria. The studies were assessed for quality without knowledge of the results. There was one excellent study,[105] three good studies,[106,107,114] and eight fair studies.[91,105,108-110,112,113,115]

Each study was examined for outcome measures such as pain, functional capacity, or a global measure of improvement. When meta-analytically combined, the studies showed a trend toward greater improvement in the patients treated with muscle relaxants, but did not reach statistical significance. Even if the findings had reached significance, statistical combinations of such study results should be interpreted with caution. The conclusion of the meta-analysis was that muscle relaxants are probably, but not certainly, more effective than placebo in decreasing symptoms of acute low back problems. However, there was not enough evidence to determine whether muscle relaxants are more or less effective than NSAIDs for reducing symptoms or whether the addition of a muscle relaxant adds to the efficacy of an NSAID.

Potential Harms and Costs. Potential complications of muscle relaxants include drowsiness and dizziness, reported to be up to 30 percent higher in patients taking muscle relaxants compared with patients taking placebos.[111] The cost of muscle relaxants is considered low to moderate.

Summary of Findings. There is moderate research evidence that muscle relaxants are more effective than placebo, but no evidence that they are better than NSAIDs, in relieving symptoms of acute low back problems. These medications have substantial potential side effects, especially a high incidence of drowsiness.

Opioid Analgesics

Panel findings and recommendations:

- When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. (Strength of Evidence = C.)
- Opioids appear to be no more effective in relieving low back symptoms than safer analgesics, such as acetaminophen or aspirin or other NSAIDs. (Strength of Evidence = C.)
- Clinicians should be aware of the side effects of opioids, such as decreased reaction time, clouded judgment, and drowsiness, which lead to early discontinuation by as many as 35 percent of patients. (Strength of Evidence = C.)
- Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. (Strength of Evidence = C.)

Oral opioid analgesics commonly given to patients with acute low back problems include morphine derivatives (opioids) and synthetic opioids. The therapeutic objective in treating low back problems is temporary pain relief.

Literature Reviewed. No RCTs were found that compared opioid analgesics (either alone or in combination with other drugs) to a placebo. Therefore, three studies were evaluated that compared opioid analgesics to other medications,[113-117] recognizing that results of the evaluation would not entirely answer the question of whether opioids are any better than placebo for back symptoms. Another article[118] contained information used by the panel.

Evidence on Efficacy. All three studies evaluated patients with acute low back problems, but with a mixed group of medications. Two reports compared acetaminophen with codeine to diflunisal (an NSAID) with patients treated for 1 and 2 weeks, respectively.[113,116] The third study compared three groups, one group receiving codeine, one oxycodone plus aspirin, and one acetaminophen.[117]

At the conclusion of treatment, Muncie, King, and DeForge[116] and Brown, Bodison, Dixon, et al.[113] found no significant differences between groups in terms of pain relief or functional improvement.

Wiesel, Cuckler, Deluca, et al.,[117] who evaluated a population of military recruits with acute low back pain, found no difference between the three medication groups in amount of time before patients returned to full activities. Pain relief was claimed to be superior in groups receiving opioid analgesics compared with acetaminophen, with the greatest effect seen in the first 3 days of treatment. No statistics were reported to support the claim.

Potential Harms and Costs. Side effects reported by subjects receiving acetaminophen with codeine included dizziness, fatigue, inability to concentrate, impaired vision, drowsiness, nausea, and constipation.[113,116] In one study, 35 percent of subjects receiving acetaminophen with codeine had to discontinue the medication because of intolerable side effects.[116] Prolonged use of opioid analgesics is associated with the development of tolerance and physical dependence. A risk of developing physical dependence with short-term use of opioids has also been reported.[111]

The expense of treatment with these medications varies greatly, depending on the medication used and the length of treatment.

Summary of Findings. There are no well-designed controlled studies that evaluate the use of opioid analgesics compared with no treatment in patients with acute low back problems. The studies reviewed found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, two studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems.

Oral Steroids

Panel findings and recommendations:

- Oral steroids are not recommended for the treatment of acute low back problems. (Strength of Evidence = C.)
- A potential for severe side effects is associated with the extended use of oral steroids or the short-term use of steroids in high doses. (Strength of Evidence = D.)

Oral steroids (corticosteroids) are used by some clinicians in the treatment of patients with acute low back problems. The therapeutic objective is to reduce inflammation in an attempt to promote healing and reduce pain.

Literature Reviewed. Of six articles screened for this topic, the only one meeting criteria for review was Halmovic and Beresford.[119] Two other articles also contained information used by the panel.[118,120]

Evidence on Efficacy. Halmovic and Beresford,[119] in a double-blind RCT, evaluated patients with low back pain who had findings of a single nerve root irritation (symptom duration of patients not specified). Patients were randomly assigned to receive a 1-week course of either an oral dexamethasone or a placebo. On followup at the end of treatment and at 1 year, no significant differences were found between the two groups in terms of pain relief.

Potential Harms and Costs. The incidence of side effects associated with steroids correlates with the potency of the drug, dosage, and duration of administration. Well-recognized complications from the prolonged use of oral steroids include suppression of pituitary–adrenal function, fluid and electrolyte disturbance, hyperglycemia, demineralization of bone, and immunosuppression (with increased susceptibility to infection). While many of these effects can be reduced or eliminated with alternate-day therapy, even short-term daily use of high-dose steroids can contribute to posterior subcapsular cataract formation, myopathy, central nervous system disturbance, and avascular necrosis of bone, especially of the femoral head.[120,121]

The expense of treatment varies greatly, depending on the medication used and the length of treatment.

Summary of Findings. The limited available research evidence indicates that oral steroids do not appear to be an effective treatment for patients with acute low back problems. Serious potential complications are associated with long-term use, but potential complications appear minimal with short-term use.

Colchicine

Panel findings and recommendations:

Based on conflicting evidence of effectiveness as well as the potential for serious side effects, colchicine is not recommended for treating patients with acute low back problems. (Strength of Evidence = B.)

Colchicine has been used primarily to treat acute attacks of gouty arthritis and can be administered intravenously or orally. The therapeutic objective of using the drug in patients with acute low back problems is to reduce inflammation and thereby reduce pain.

Literature Reviewed. Of 13 articles screened, 3 RCTs met criteria for review.[122-124] Schnebel and Simmons[122] evaluated only patients with acute low back problems of less than 3 months' duration. Mock, Gladice, McFadden, et al.[123] evaluated patients with symptoms of more than 2 months. Simmons, Harris, Koulisis, et al.[124] evaluated those with symptoms lasting up to 6 months.

Evidence on Efficacy. Schnebel and Simmons[122] found no statistically significant difference between colchicine and a placebo, although the oral colchicine group did have significantly more diarrhea and vomiting than the placebo group. Simmons, Harris, Koulisis, et al.,[124] who compared groups receiving either intravenous colchicine or intravenous saline, found significantly improved pain ratings for the colchicine group, but pain relief was short-lived (lasting from 1 hour to 2 days). Also, two patients in the colchicine group developed complications (diarrhea and a local inflammatory response). Mock, Gladice, McFadden, et al.,[123] who evaluated for 1 month a group receiving one dose of intravenous colchicine followed by oral colchicine, compared with a group receiving placebo, found significantly greater pain relief in the colchicine group.

Potential Harms and Costs. Potential complications from the use of colchicine are gastrointestinal irritation, skin problems, severe chemical cellulitis from intravenous infiltration, and bone marrow suppression with agranulocytosis.[124] The expense of treatment with colchicine varies greatly, depending on whether oral or intravenous administration is used and on length of treatment.

Summary of Findings. Research evidence is limited and conflicting on whether colchicine, given either orally or intravenously, is an effective treatment for patients with acute low back problems. Serious potential side effects have been reported with use of this medication.

Antidepressant Medications

Panel findings and recommendations:

Antidepressant medications are not recommended for the treatment of acute low back problems. (Strength of Evidence = C.)

Antidepressant medications have been widely used for both depressed and nondepressed patients with chronic low back problems. The extent to which these medications are used in treating patients with acute low back problems is unknown. Some researchers have hypothesized that the medications may possibly have a pain-relieving effect in addition to antidepressant properties. If so, the medications could help some patients who have chronic pain whether or not the patients are also depressed. The therapeutic objective of using antidepressant medications for low back problems is to reduce pain.

Literature Reviewed. Of 18 articles screened, 3 RCTs met review criteria.[125-127] Other articles also contained information used by the panel.[124,128]

Evidence on Efficacy. No studies were found evaluating the efficacy of antidepressant medications for treatment of acute low back problems. The three studies reviewed all compared an antidepressant medication to a placebo in a double-blind fashion in patients with chronic, not acute, low back pain. These studies all randomized patients to receive either a

pharmacologically inert placebo or an antidepressant medication. Alcoff, Jones, Rust, et al.[illegible] used imipramine, as did Jenkins, Ebbutt, and Evans.[illegible] Goodkin, Guillon, and Agras[illegible] used trazodone. The studies found no significant differences between groups receiving antidepressant and placebo in terms of pain reduction, functional limitations, depression, or the use of opioids. All three studies had methodological flaws, including small sample sizes, lack of power calculations, and incomplete description of followup.

Potential Harms and Costs. Antidepressant medications can produce a variety of side effects including dry mouth, drowsiness, constipation, urinary retention, orthostatic hypotension, and mania.[illegible]

The cost of treatment with antidepressant medications can vary from low to high depending on the medication used, dose, and length of treatment.

Summary of Findings. No studies were found that evaluated the efficacy of antidepressant medications for treatment of acute low back problems. The studies reviewed all evaluated patients with chronic low back problems. They found no significant differences between antidepressants and placebo on any outcome measured. Numerous reported side effects are associated with antidepressant medications, but the potential for serious side effects is small in otherwise healthy adults.

Symptom Control: Physical Treatments

Spinal Manipulation

Panel findings and recommendations:

- Manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. (Strength of Evidence = B.)
- When findings suggest progressive or severe neurologic deficits, an appropriate diagnostic assessment to rule out serious neurologic conditions is indicated before beginning manipulation therapy. (Strength of Evidence = D.)
- There is insufficient evidence to recommend manipulation for patients with radiculopathy. (Strength of Evidence = C.)
- A trial of manipulation in patients without radiculopathy with symptoms longer than a month is probably safe, but efficacy is unproven. (Strength of Evidence = C.)
- If manipulation has not resulted in symptomatic improvement that allows increased function after 1 month of treatment, manipulation therapy should be stopped and the patient reevaluated. (Strength of Evidence = D.)

Spinal manipulation includes many different techniques. For this guideline, manipulation is defined as manual therapy in which loads are applied to the spine using short or long lever methods. The selected joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation include symptomatic relief and functional improvement.

Literature Reviewed. Of the 112 articles screened for this topic, 13 reporting on 12 RCTs met criteria for review.[illegible]

The panel also considered recent meta-analyses and cost analyses.[141-144] In addition, the panel used information from articles that did not meet selection criteria.[illegible]

Evidence on Efficacy. The meta-analysis by Shekelle, Adams, Chassin, et al.[144] was based on 29 controlled trials of manipulation for low back problems. Nine of the studies used in the meta-analysis focused on patients with acute low back problems and tested the effect of manipulation against sham manipulation[illegible] or various other conservative treatments.[illegible]

Of those RCTs that evaluated manipulation in patients with acute low back pain, the two highest quality studies used similar research designs.[illegible] Both these studies randomly assigned patients to either a group receiving manipulation or a nontreatment control group, with patients stratified by whether symptoms had lasted less than 14 days, 14 to 28 days, or over 28 days in one study.[177] For patients with 14 to 28 days of symptoms, both studies found the manipulation groups had statistically significant improvement in pain relief and functioning compared with the control groups. However, this effect was only seen within the first 2 weeks after starting treatment. For patients with symptoms of less than 14 days or over 28 days, no differences in improvement were found between the manipulation and control groups for any followup times.

A meta-analysis of the remaining seven studies also showed statistically significant short-term effects of manipulation in hastening recovery from low back problems.[144] Another meta-analysis, based on 23 randomized controlled trials of manipulation or mobilization, came to a similar conclusion.[141] This analysis indicated that, in patients with acute low back problems without radiculopathy, manipulation reduces pain and has positive short-term impact on daily functioning. Most studies have concentrated upon outcomes assessed within the first month of care.

The meta-analysis by Shekelle, Adams, Chassin, et al.[144] analyzed, in addition, studies of spinal manipulation in patient groups who had predominantly chronic low back problems, a mix of acute and chronic low back problems, or pain of undetermined duration. Studies of manipulation in these groups had conflicting results concerning the efficacy of manipulation.

Shekelle, Adams, Chassin, et al.[144] also analyzed three studies on the use of spinal manipulation for patients with low back problems who had radiculopathy, but concluded that the evidence was insufficient to demonstrate efficacy.[illegible]

Potential Harms and Costs. Shekelle, Adams, Chassin, et al.[144] described published case reports of patients presenting with sciatica who had

increasing neurolo[illegible]erioration following manipulation, but estimated that the risk of se[illegible]omplications from lumbar spinal manipulation is small and may vary with the clinical condition with which the patient presents. No systematic report of frequency of complications from spinal manipulative therapy has been published. Mandell, Lipton, Bernstein, et al.[147] listed autonomic disturbances such as faintness, perspiration, and hyperventilation as common short-term reactions to manipulation. The total cost of manipulative therapy is determined by the frequency and duration of care.

Summary of Findings. The evidence for effectiveness of manipulation varies depending on the duration and nature of the patient's presenting symptoms. For patients with acute low back symptoms without radiculopathy, the scientific evidence suggests spinal manipulation is effective in reducing pain and perhaps speeding recovery within the first month of symptoms. For patients whose low back problems persist beyond 1 month, the scientific evidence on effectiveness of manipulation was found to be inconclusive. For patients with radiculopathy, the scientific evidence was also inconclusive about either the effectiveness or the potential harms of manipulation. Finally, the panel offered the opinion that, for patients with acute low back problems and findings of possible progressive or severe neurologic deficits, assessment to rule out serious neurologic conditions is indicated before initiating manipulation therapy.

Physical Agents and Modalities

Panel findings and recommendations:

The use of physical agents and modalities in the treatment of acute low back problems is of insufficiently proven benefit to justify their cost. As an option, patients may be taught self-application of heat or cold to the back at home. (Strength of Evidence = C.)

Physical agents and modalities include ice, heat (including diathermy), massage, ultrasound, cutaneous laser treatment, and electrical stimulation (not transcutaneous electrical nerve stimulation or TENS). The therapeutic objective of physical agents and modalities is to provide symptomatic relief and, for some modalities, to reduce inflammation, "muscular symptoms," or joint stiffness.

Literature Reviewed. Of 25 articles screened for this topic, 10 reporting on 8 RCTs met criteria for review.[148,149,150,151,152,153,154,155]

Evidence on Efficacy. Many studies compared different combinations of physical agents and modalities, making it difficult to evaluate effectiveness of specific modalities. Only two studies evaluated physical agents and modalities in patients with acute low back pain.[148,149] Neither found significant differences in self-rated pain relief or other outcome measures between patient groups receiving physical agents and modalities (including diathermy, ultrasound, flexion/ex[illegible] exercises, massage, and electrotherapy) and groups receiv[illegible] placebo.

The other studies reported on groups of either chronic or a mix of acute and chronic low back pain patients. Three studies found no significant differences in patient-reported outcome measures between treatments (including cutaneous laser, diathermy, electrotherapy, exercise, heat, massage, and ultrasound) and a placebo.[150,151,152] Manniche, Hesselsoe, Bentzen, et al.[153] found intensive back-strengthening exercises superior to physical agents and modalities on patient-rated outcome measures, but the group receiving physical agents/modality treatment was not compared with a control group receiving no intervention. Melzack, Vetere, and Finch[154] found that a group receiving TENS therapy had greater pain relief than a group receiving massage therapy. Again, treatments were not compared with a no-intervention control. Linton, Bradley, Jensen, et al.[155] found that a group given a combination of physical agents and modalities, ergonomic education, and behavioral therapy had significantly better outcomes than a control group receiving no intervention, but the effect of physical agents and modalities could not be determined.

Potential Harms and Costs. Risks from potential complications of physical agents and modalities are believed to be small. A possible exception is in pregnant patients, for whom ultrasound and diathermy are not recommended because of theoretical risks to the fetus.

The costs of individual treatment sessions using physical agents and modalities are variable, determined by the number of modalities used, the length of treatment, and the number of treatment visits.

Summary of Findings. No well-designed controlled trials support the use of physical agents and modalities as treatments for acute low back problems. However, some patients with acute low back problems appear to have temporary symptomatic relief with physical agents and modalities. Therefore, self-administered home programs for modalities involving heat or cold are considered a treatment option.

Transcutaneous Electrical Nerve Stimulation

Panel findings and recommendations:

Transcutaneous electrical nerve stimulation (TENS) is not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

A TENS unit is a small battery-operated device worn by the patient. It provides continuous pulses of electricity by way of surface electrodes. Presumably, TENS produces a counter-stimulation of the nervous system, which can modify pain perception. The therapeutic objective of TENS in patients with low back problems is to provide symptomatic pain relief.

Literature Reviewed. Of 34 articles screened for this topic, 9 articles reporting on 8 RCTs met criteria for review.[146-154] Only one study evaluated patients with acute low back pain.[149]

Evidence on Efficacy. Hackett, Seddon, and Kaminski[149] evaluated a treatment called "electroacupuncture," which consisted of low-amplitude pulsed electrical current administered by way of surface electrodes rather than by needles. The panel considered this a variation of TENS rather than a type of acupuncture since no needling was involved. For the study, 37 patients with low back pain of less than 3 days' duration were randomly assigned to groups receiving either two 15-minute treatments of electroacupuncture and placebo tablets or paracetamol tablets and placebo electroacupuncture with no current applied. There was no difference in results at 1 and 2 weeks. By the sixth week after the initial treatment, patients who had electroacupuncture reported significantly less pain, measured on a visual analog pain-rating scale, compared with those who took paracetamol.

The other studies reviewed focused on patients with chronic low back pain or other types of chronic pain or on a mixture of acute and chronic low back pain patients. The largest randomized study of TENS was carefully blinded and found no benefit for TENS over sham TENS in patients with chronic low back problems.[147] The remaining studies were of variable quality and were inconclusive regarding efficacy of TENS for relieving chronic pain.

Potential Harms and Costs. The risks of TENS are considered low. The cost of this treatment is considered low to moderate (depending upon whether the equipment is rented or owned by the patient).

Summary of Findings. There is inconclusive evidence of the efficacy of TENS in patients with acute low back problems. Only one published study addresses this issue, and its findings are considered weak.

Shoe Insoles and Shoe Lifts

Panel findings and recommendations:

- Shoe insoles may be effective for patients with acute low back problems who stand for prolonged periods of time. Given the low cost and low potential for harms, shoe insoles are a treatment option. (Strength of Evidence = C.)
- Shoe lifts are not recommended for treatment of acute low back problems when lower limb length difference is ≤2 cm. (Strength of Evidence = D.)

Shoe insoles (or inserts) are devices placed inside shoes that may vary from over-the-counter foam or rubber inserts to custom-made orthotics. The therapeutic objective of shoe inserts is the reduction of back pain.

Shoe lifts (or raises) are additions made to the heel or sole of a shoe to increase its height. The therapeutic objective of shoe lifts is to compensate for lower limb length inequality and thereby reduce back pain.

Literature Reviewed. Of seven articles reviewed for this topic, only one was an RCT that met criteria for review.[143] Other articles contained information used by the panel, but did not meet article selection criteria.[144-150]

Evidence on Efficacy. Basford and Smith[143] used a randomized crossover design to evaluate the use of shoe insoles compared with no insoles in adults with mild back pain who spent at least 75 percent of each workday standing. Of 39 subjects studied, 44 percent reported reduced back pain when using the insoles, 3 percent reported increased back pain, and 51 percent reported no difference. Of the subjects who reported no improvement, many stated that their shoes were too tight to allow insoles to be added comfortably.

There were no controlled trials that evaluated shoe lifts in patients with either acute or chronic low back problems. The extent to which leg length inequality might be associated with low back problems has not been established. Lower limb length differences of up to 2 cm are frequently seen in subjects with no history of low back problems.[145,146] One study evaluated aircraft industry workers and found no correlation between a 2-cm limb length inequality and either previous back problems or later reports of back complaints.[144]

Potential Harms and Costs. Shoe insoles and shoe lifts are low-risk treatments; their cost varies from low (for ready-made items) to moderate (for custom-made orthotics).

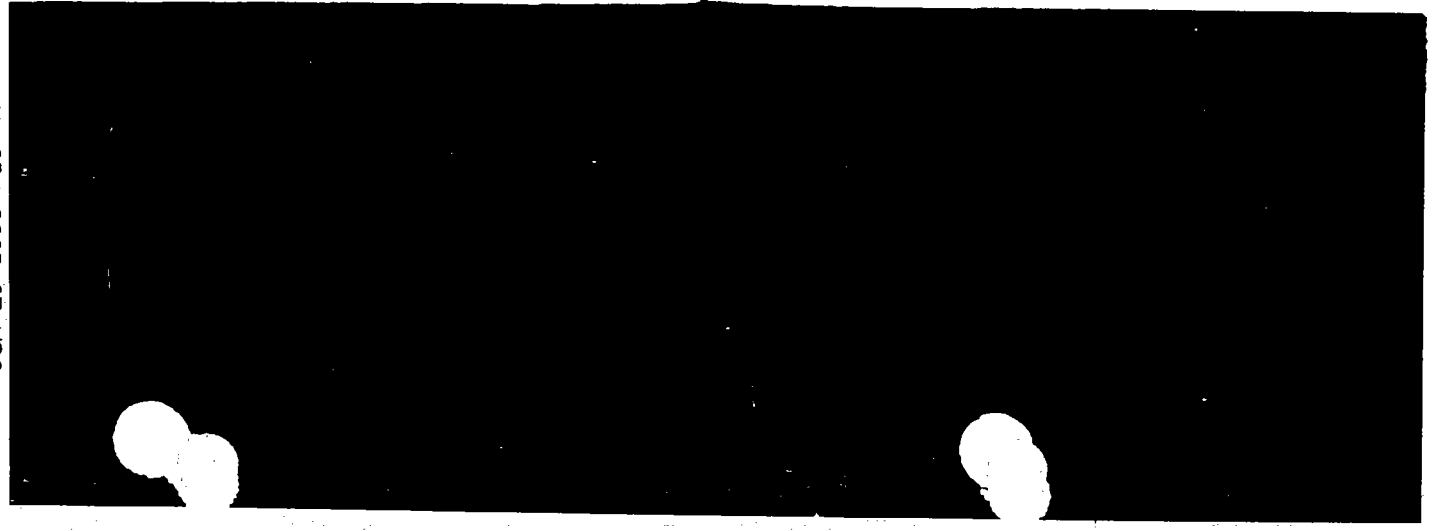
Summary of Findings. Limited evidence (one crossover study) indicates that shoe insoles may reduce back pain in some individuals with mild back complaints. There is no evidence they provide any long-term benefit. The extent to which leg length inequality might be associated with acute low back problems has not been established, although differences of less than 2 cm are unlikely to be problematic.

Lumbar Corsets and Back Belts

Panel findings and recommendations:

- Lumbar corsets and support belts have not been proven beneficial for treating patients with acute low back problems. (Strength of Evidence = D.)
- Lumbar corsets, used preventively, may reduce time lost from work due to low back problems in individuals required to do frequent lifting at work. (Strength of Evidence = C.)

Lumbar support devices for low back problems include lumbar corsets and support belts, back braces and molded jackets, and back rests for chairs and car seats. The panel decided to evaluate only lumbar corsets and



support belts for l[illegible]deline. Among theories on why lumbar corsets and support belts mig[illegible]treat or prevent low back problems are that they compress the abdo[illegible] (causing increased intra-abdominal pressure, which unloads the vertebral column) and/or that they act as a mechanical reminder to decrease bending. Therapeutic objectives of lumbar supports are to control pain and/or protect against injury.

Literature Reviewed. Of 31 articles screened, 3 RCTs about lumbar corsets and support belts met review criteria for adequate evidence about efficacy.[10,16,18] Another article contained information used by the panel, but did not meet selection criteria.[19] None of these studies evaluated only patients with acute low back problems. One evaluated only chronic low back pain patients.[17] One evaluated a mixed group of acute and chronic low back pain patients.[10] The other two studies evaluated the prevention of low back problems in workers doing frequent lifting tasks.[16,18]

Evidence on Efficacy. Coxhead, Meade, Inskip, et al.[11] compared lumbar corset use to traction, exercise, and manipulation but included other interventions, making the direct effect of corset use difficult to determine.

Million, Hasvik Nilsen, Jayson, et al.[17] compared the use of two types of lumbar corsets, one with and one without a lumbar support, in patients with chronic low back problems (all with symptoms longer than 6 months). This study was an RCT, but had too few subjects to meet review criteria. Although this study found a considerable and significant improvement in symptoms in the group wearing corsets with a lumbar support, no control group was used in the study to ascertain the effect of corset use as compared with no corset use.

Walsh and Schwartz,[18] in an RCT, evaluated 90 grocery warehouse workers not currently receiving treatment for low back problems. Subjects were randomly assigned to three groups. One group received a custom-molded lumbar corset plus a 1-hour training program on proper lifting, one the training program alone, and one no intervention. During the 6-month study period, no significant differences were reported between groups in back injury rates or in time lost from work due to back problems. However, the group assigned to lumbar corsets plus training showed significantly less time lost from work due to back symptoms during the 6 months of the study when compared with the prior 6-month period. No similar significant effect was found for the other two groups.

Reddell, Congleton, Huchingson, et al.,[16] in an RCT, evaluated 642 airline baggage handlers randomly assigned to use of a lumbar weightlifting belt, with and without a supplemental training class, or to the training class alone, or to no intervention. The 1-hour training course included instruction on proper lifting techniques, and employees were given stretching exercises to be done before each flight. Over an 8-month period, no significant differences were found between groups studied in back injury claims or in days lost from work. However, the validity of these results is questionable since 58 percent of workers assigned to wear weightlifting belts stopped using them before the end of the study period.

Potential Harms and Costs. S[illegible]thors suggest that the prolonged use of lumbar corsets and support b[illegible]ay lead to a decrease in strength of abdominal and back muscles, but no clear evidence of this was found in patients with low back problems. Walsh and Schwartz[18] found that no such weakness occurred in workers who wore lumbar corsets for 6 months as a preventive measure. In the study by Reddell, Congleton, Huchingson, et al.,[16] the majority of workers who stopped wearing weightlifting belts complained that the belts were too hot and/or too uncomfortable.

The cost of lumbar corsets and support belts varies from low to moderately expensive.

Summary of Findings. There is no evidence that lumbar corsets or support belts are effective for treating acute low back problems and conflicting evidence on whether lumbar corsets and support belts are effective for preventing or reducing the impact of low back problems in subjects who do frequent lifting at work.

Traction

Panel findings and recommendations:

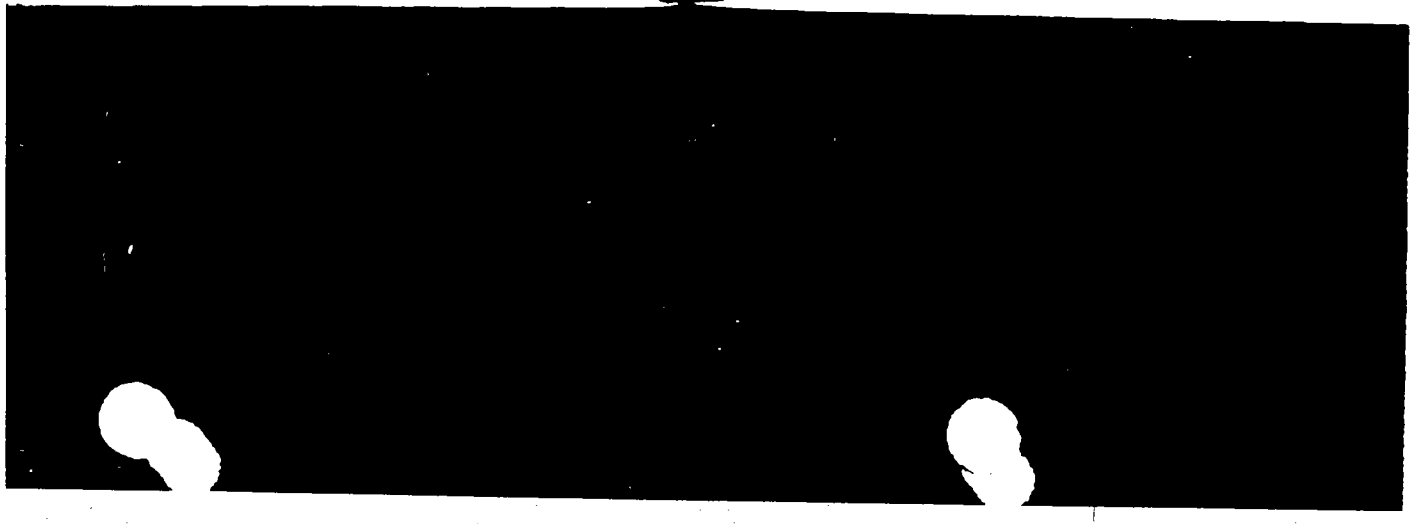
Spinal traction is not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = B.)

Traction, when used for low back problems, involves the application of intermittent or continuous force along the axis of the spine in an attempt to elongate the spine by either mechanical or manual means. The most common type used for low back pain is pelvic traction, in which a snug girdle around the pelvis is attached to weights hung at the foot of the bed. The therapeutic objective of traction for patients with low back problems is to reduce pain.

Literature Reviewed. Of 31 articles screened for this topic, 7 articles reporting on 6 RCTs met criteria for review.[12,13,15,17] Another article contained information used by the panel, but did not meet selection criteria.[19]

Evidence on Efficacy. A meta-analysis of the studies on traction was done by the panel methodologists. Quality rating was done for the six RCTs reviewed without knowledge of study results. There were no excellent studies, one good study,[17] three fair studies,[12,13,15] a fair study reported on by Mathews, Mills, Jenkins, et al.,[14] and one poor study.[13]

All the studies involved patients with acute low back pain of less than 3 months' duration, but studies varied on whether patients with a history of previous low back problems were excluded. Groups receiving traction were compared with groups receiving sham traction.[12,13] Traction combined with bed rest and corset use was compared with bed rest and corset use alone.[12] Traction was compared with heat[14] and with isometric exercise.[13] In addition, Coxhead, Meade, Inskip, et al.[11] studied groups receiving various combinations of traction, manipulation, exercise, and corset use in



a multifactorial design with 16 cells. The six studies varied with respect to types of traction, control groups, outcome measures, and assessment periods. For this reason, no attempt was made to quantitatively combine these data.

Five of the six studies showed no difference between traction and the comparison group. In one study, the group treated with bed rest and corset use combined with traction had less pain at 1 week than those receiving bed rest and corset use without traction, but this difference was gone by 3 weeks.[172] Moreover, some criticize this study because of attention bias against those in the control group. In general, the studies did not indicate that traction in any form is beneficial in terms of pain relief, physiological status, length of hospital stay, functional outcome, or perception of overall improvement for patients with acute low back problems. The studies were too small to determine if traction actually harms patients with acute low back problems.

Potential Harms and Costs. The potential harms from traction relate to debilitation due to prolonged bed rest, including loss of muscle tone, bone demineralization, and the risk of thrombophlebitis. There is added risk of increased intraocular pressure and blood pressure with inverted hanging traction.[174] The cost of traction is considered low to moderate if it is done on an outpatient basis, or high if the patient is hospitalized for traction.

Summary of Findings. Evidence does not demonstrate traction to be effective in the treatment of patients with acute low back problems.

Biofeedback

Panel findings and recommendations:

Biofeedback is not recommended for treatment of patients with acute low back problems. (Strength of Evidence = C.)

Biofeedback involves translating the physiologic activity of a patient's muscular response into a visual or auditory signal that allows the patient to try to facilitate or inhibit the muscular activity. The therapeutic objective is to reduce muscle tension and thereby reduce pain. Biofeedback has been advocated primarily for patients with chronic low back problems.

Literature Reviewed. Of 13 articles screened for this topic, 4 reporting on 5 RCTs met criteria for review.[175-178] Other studies did not meet panel review criteria because they had fewer than 10 subjects per treatment group, but were used in a meta-analysis.[161,168] All of the studies involved patients with chronic low back pain. In most subjects, pain had persisted for several years.

Evidence on Efficacy. Because these trials presented conflicting results, a meta-analysis was begun by the panel methodologists. Studies were assessed for quality without knowledge of the results. There were no excellent studies, one good study,[175] three fair studies,[177,161,178] and a fair

study reported by Flor, Haag, Turk, et al.[176] and by Flor, Haag, and Turk.[161] There were no poor studies.

The studies involved comparisons of biofeedback with sham biofeedback,[161,175,177] biofeedback combined with another treatment in comparison with the other treatment alone,[177] and biofeedback alone compared with some other treatment.[161,176,178]

The study with a "good" quality rating showed no benefit for biofeedback over sham biofeedback.[175] Two studies reported patients in the biofeedback groups developed significantly better control of paraspinous muscle electromyographic activity.[175,176] In neither study did this reduce pain. Thus, of the five studies, two showed no benefit for biofeedback.[161,168] Two showed a benefit for biofeedback: Aarbur, Khalil, Wahy, et al.[177] and the study reported by Flor, Haag, Turk, et al.,[176] and by Flor, Haag, and Turk.[161] One study showed a slight benefit for biofeedback compared with a placebo condition, but reported an even better benefit for relaxation training.[178] Statistical combination of results from these studies was not done because it would require requesting the original data from the authors.

Conclusions from the attempted meta-analysis were that biofeedback as a treatment for low back problems has been studied only for chronic problems, and that most of the studies are of mediocre quality and arrive at conflicting results.

Potential Harms and Costs. The risks for biofeedback are considered low. The costs of biofeedback treatment are determined by the number of treatment visits.

Summary of Findings. There is conflicting evidence on the effectiveness of biofeedback for treating patients with chronic low back problems. However, this technique has not been studied in patients with acute low back problems.

Symptom Control: Injection Therapy

Trigger Point and Ligamentous Injections

Panel findings and recommendations:

- **Trigger point injections are invasive and not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)**
- **Ligamentous and sclerosant injections are invasive and not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)**

Trigger point injections involve the injection of local anesthetic into soft tissues (muscles) near localized tender points in the paravertebral area.[148] The theory that such trigger points are responsible for causing or perpetuating low back pain is controversial and disputed by many experts. Other articles reviewed for this topic involve the injection of various

substances (es 'y sclerosing agents) into interspinal ligaments and ligamentous a attachments in the low back. The theory behind such treatment is tha. as stimulates formation of scar tissue in ligaments. The therapeutic objective of both trigger point injections and ligamentous injections is to reduce low back pain.

Literature Reviewed. Of 14 articles screened for the topics of trigger point and ligamentous injections, 6 RCTs met criteria for review. Three of these evaluated trigger point injections into muscle.[128-130] Three evaluated injections into ligamentous structures in the back.[126-128] Other articles contained information used by the panel, but did not meet article selection criteria.[126-139]

Evidence on Efficacy. Of the articles evaluating trigger point injections, only Frost, Jessen, and Siggaard-Andersen[134] evaluated patients with acute low back problems. The study population, however, included patients with acute neck or shoulder pain, and data were not given separately for the patients with low back problems. For the other two RCTs on trigger point injections, either the patients evaluated had chronic low back problems[130] or the duration of symptoms was not reported.[129]

Various medications were used for trigger point injections. Frost, Jessen, and Siggaard-Andersen[134] had two groups receiving either local anesthetic or saline. Bourne[130] had three groups receiving methylprednisolone and lignocaine, or triamcinolone and lignocaine, or lignocaine alone. Garvey, Marks, and Wiesel[132] had four groups receiving lidocaine alone, or lidocaine combined with a steroid, or needle acupuncture (with no injection of material), or vapocoolant spray to the skin followed by acupressure (using a plastic needle guard). Two studies included control groups who had no medication injected into muscles,[132,134] but none of the three studies included a group with no intervention.

Frost, Jessen, and Siggaard-Andersen[134] and Garvey, Marks, and Wiesel[132] found no differences between groups in pain relief or other outcome measures on followup at 1 and 2 weeks posttreatment, respectively. Bourne[130] found significantly greater pain relief at 3 months followup for the two groups receiving steroid injections than for the group receiving injections of local anesthetic alone.

Of the three articles evaluating injections into ligamentous structures, two studies evaluated patient groups including some patients with acute low back problems.[126,128] One study evaluated a subgroup of patients with acute low back problems, all with pain over the medial iliac crest.[126] In the other study, patients were only described as having low back problems for greater than 1 month's duration without specifying how many patients had either acute or chronic symptoms.[126] The third article evaluating ligamentous injections evaluated only patients with chronic low back problems.[127]

Various substances were injected into different ligamentous structures of the low back. Collée, Dijkmans, Vandenbroucke, et al.[126] studied groups receiving injections of either local anesthetic or saline into an area of

tenderness over the media' rest (not specified if into muscle or ligamentous attachments). /, Klein, Dorman, et al.[127] evaluated groups receiving injections of either a dilute phenol solution (sclerosing agent) or saline into the lumbar interspinal ligament. Somne, Christensen, Hansen, et al.[128] evaluated groups receiving injections of either a combination of local anesthetic and steroid or saline alone into the lumbar ligament.

Collée, Dijkmans, Vandenbroucke, et al.[126] found that for patients with acute low back pain, there was no significant difference in pain relief between the saline or anesthetic groups, either immediately postinjection or at 1 or 2 weeks followup. Ongley, Klein, Dorman, et al.[127] found greater improvement in pain and disability scores for the patients receiving phenol injections (intended to induce scar) as compared with saline. Somne, Christensen, Hansen, et al.[128] found that the group receiving injections with a combination of steroid and local anesthetic had significantly greater improvement in symptoms at 2 weeks followup than did the group receiving injections with saline.

Potential Harms and Costs. The potential risks of trigger point injections include damage to nerves or other tissues, infection, and hemorrhage.[130] The cost for this treatment is considered low to moderate.

Summary of Findings. Based on limited research evidence in studies that included patients with chronic problems, the efficacy of trigger point or ligamentous injections for treating acute low back problems appears equivocal. The injections can expose patients to serious potential complications.

Facet Joint Injections

Panel findings and recommendations:

Facet joint injections are invasive and not recommended for use in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

In treatment of low back problems, facet joint injections involve the injection of local anesthetics and/or corticosteroids into or around facet joints of the lumbar spine, with needle placement aided by fluoroscopy. The theoretical basis is that some patients with low back problems have a "facet syndrome" with pain arising from facet joints. The facet syndrome reportedly involves patients with primarily low back pain (unilateral or bilateral) and no root tension signs or neurologic deficits, the pain usually being aggravated by extension of the spine.[81] The therapeutic objective of facet joint injections is temporary relief from motion-limiting pain so the patient may proceed into an appropriate exercise program.[117]

Literature Reviewed. Of 17 articles screened for this topic, 5 RCTs met review criteria.[121-125] Other articles contained information used by the panel, but did not meet criteria.[126,127]

Evidence on Efficacy. No articles were found evaluating patient groups who had only acute low back problems of less than 3 months' duration. One study evaluated a mixed group of acute and chronic patients with pretreatment symptom durations ranging from 1 to 12 months.[121] Three articles evaluated patients with low back pain of over 3 months' duration.[122-124] One study did not specify symptom duration before treatment.[125]

Injections were made either into facet joints or into periscapular areas around facet joints. The latter type of injection was also referred to as a "facet nerve block" when a local anesthetic was used. Medications injected included steroids, local anesthetics, and saline (either alone or in combination).

Three studies evaluated a combination of steroid and local anesthetic injected into either facet joints or periscapular areas.[123-125] Three studies evaluated groups receiving facet joint injections in which steroid was compared with saline,[122] or local anesthetic was compared with saline,[121] or a combination of steroid and local anesthetic was compared with saline.[123]

None of the five studies that met review criteria found any significant differences between groups for patient-rated pain relief or global improvement scores during followup periods of up to 3 months after treatment. The only study with followup beyond 3 months found significantly greater improvement in pain and functional disability ratings at 6 months followup for the group receiving steroid facet injections compared with saline facet injections, but no significant differences between groups in number of patients who had sustained improvement over the entire 6-month followup period.[122]

Potential Harms and Costs. Some of the articles reviewed noted transient local pain at the injection sites. The risks of facet joint injections include potential infection, hemorrhage, neurologic damage, and chemical meningitis,[116,117] as well as x-ray exposure from fluoroscopy. Facet injections are considered a moderate- to high-cost treatment.

Summary of Findings. No studies have adequately investigated the efficacy of facet injections for patients with acute low back problems. However, there were an adequate number of studies evaluating facet injections for chronic low back problems.[116-120] One study evaluated a mix of acute and chronic problems.[121] Neither the type of agent injected (steroid, local anesthetic, saline, or a combination of these) nor the location of the injection (intrafacet or periscapular) made a significant difference in patient outcomes during the first 3 months after treatment or in the percentage of patients with sustained improvement over 6 months.

Based on limited research evidence, facet joint injections appear to be associated with rare potential serious complications and do not appear to be effective for treating acute low back problems.

Epidural Injections (Steroids, Lidocaine, Opioids)

Panel findings and recommendations:

- There is no evidence to support the use of invasive epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Strength of Evidence = D.)
- Epidural steroid injections are an option for short-term relief of radicular pain after failure of conservative treatment and as a means of avoiding surgery. (Strength of Evidence = C.)

Epidural injections for treating low back problems, done primarily in patients with suspected radiculopathy, involve the injection of medication (corticosteroids, local anesthetics, or narcotics) into the epidural space, near the site where the nerve roots pass before entering the intervertebral foramen. In theory, injecting medication into the epidural space allows a concentrated amount of medication to be deposited and retained in a specific area, exposing the nerves to the medication for a prolonged period of time. The therapeutic objective of epidural injections is to reduce swelling, inflammation, and pain.

There are various techniques for performing the epidural injection, some of which are more precise than others.[126] According to White,[126] placement of epidural needles is incorrect in 25 percent of the cases.

Literature Reviewed. Of 76 articles screened for this topic, 9 RCTs met criteria for review.[126,128-135] Other articles contained information used by the panel, but did not meet article selection criteria.[127,136-155]

Evidence on Efficacy. Two studies evaluated patients with acute low back pain of less than 3 months' duration and also with radicular symptoms and findings suggesting nerve root dysfunction.[134,135] Both studies compared groups receiving epidural injections of steroids combined with local anesthetic to groups receiving injections of local anesthetic alone, either into the epidural space[135] or into a tender spot over the sacrum.[134]

Cuckler, Bernini, Wiesel, et al.[135] found no significant differences in pain relief between groups immediately posttreatment or at long-term followup (mean of 20 months). Mathews, Mills, Jenkins, et al.[134] found no significant differences in pain relief between groups at 1, 6, or 12 months followup, but the epidural steroid group did have significantly better results at 3 months followup.

The remaining seven studies evaluated groups with either chronic low back problems or a mix of acute and chronic problems.[126,128-133] Medications used and locations injected varied. Four studies evaluated groups receiving epidural injections with various combinations of steroids, local anesthetics, and/or saline.[126,128,131,133] Two studies evaluated groups receiving either epidural steroid injections or injections of saline into the interspinous ligament.[130,132] One study evaluated groups receiving epidural injections with various combinations of steroids and morphine.[129]

The five studies that reported on short-term pain relief at 2 to 4 weeks followup showed conflicting results. For this time period, three studies reported significantly greater pain relief for the epidural steroid groups.[201,204,205] The other two studies found no differences in pain relief between groups.[202,207]

Five studies reported on followup beyond 1 month.[202,203,204,206,207] Only one found significantly greater pain relief for the epidural steroid group.[202] The other studies found no significant differences in pain relief between groups. One study did find that a significantly higher percentage of the group receiving epidural steroid injections had returned to work at 3 months.[204] Three studies showed significantly better results within the first month for epidural steroids versus local anesthetic or saline injections, but not on longer followup.[201,204,205] No significant differences were reported between groups at 3 months[203] or at 1 year.[201] Ridley, Kingsley, Gibson, et al.[202] did not report followup beyond 2 weeks. Two other studies found no significant differences in pain relief between groups for any followup period.[203,207] One study that evaluated epidural injections of morphine compared with (and/or in combination with) steroids found no significant differences in pain relief between groups on either short-term (within 1 month) or longer term followup.[203]

Potential Harms and Costs. Reported complications of epidural injections are described by Kepes and Duncalf.[208] The primary major complication reported was rare epidural abscess. Minor transient complications included headache, fever, and inadvertent spinal tap. Rocco, Frank, Kaul, et al.[209] reported several cases of "life-threatening ventilatory depression" in patients who received epidural injections of morphine and steroids combined. In 5 of the 19 times such injections were given, the patients experienced respiratory depression to the point of somnolence and had to receive naloxone for reversal of narcosis. Also posttreatment, the respiratory rates of patients receiving epidural morphine were lower than for patients receiving epidural steroids alone. The lowest respiratory rates were seen in those receiving injections of morphine combined with steroids. Mandell, Lipton, Bernstein, et al.[147] described headache as the most common side effect of epidural steroid injections (presumably resulting from pressure changes in the epidural space or accidental puncture of the dura) and listed aseptic meningitis, infection, and neurologic problems as other possible complications. Epidural injections are considered an expensive treatment.

Summary of Findings. Limited research evidence indicates that epidural injections using any type of medication lack proven efficacy for treating patients with acute low back pain without radiculopathy. Epidural injections are invasive and pose rare but serious potential risks. There was no evidence that epidural steroids are effective in treating acute radiculopathy, but the panel's opinion was that epidural steroid injections may be useful as an attempt to avoid surgery.

Acupuncture

Panel findings and recommendations:

Invasive needle acupuncture and other dry needling techniques are not recommended for treating patients with acute low back problems. (Strength of Evidence = D.)

Acupuncture is defined here to include all types of "dry needling" procedures (where no medication is injected) into cutaneous and subcutaneous tissues, muscles, or ligaments. Traditional acupuncture, based on Chinese philosophy, requires that needles be inserted into specific areas of the body (the prescribed Chinese meridians) and that these needles be rotated to produce a noxious stimulus. Other types of dry needling involve needle insertion without regard for the Chinese meridians into tender spots or other areas and may or may not involve the rotation of the needles. Some dry needling techniques also add electrical stimulation to the needles. The therapeutic objective of acupuncture and other dry needling techniques is to reduce pain.

Literature Reviewed. Of 24 articles screened for this topic, 8 reporting on 6 RCTs met criteria for review.[142,143,210-215] The panel also examined a meta-analysis.[216] Other articles contained information used by the panel, but did not meet article selection criteria.[217-220]

Evidence on Efficacy. All six RCTs evaluated patients with chronic back problems (with or without leg symptoms) of greater than 6 months' duration. Four of the articles reporting on three RCTs compared groups that received needling with groups that received no needling.[142,143,213,215] Needling received was either acupuncture in traditional Chinese meridians[142,143,213,215] or needle insertion into tender muscle points.[210] In these studies, the groups that received some type of needling intervention had significantly better outcomes (in pain reduction and increased activity levels) than did the groups receiving no needling.

The remaining four articles reporting on three RCTs compared groups receiving acupuncture in the traditional Chinese meridians to groups receiving various types of needle insertion in other parts of the body.[211-215] None of these studies found any significant differences between groups in any outcomes measured.

A meta-analysis, based on 51 clinical studies on acupuncture used for various types of chronic pain (including back pain), found that the quality of even the better studies was mediocre and their results highly contradictory.[216] Specifically noted was that most of these studies did not provide an appropriate control group or were not adequately blinded. None of the studies demonstrated an advantage of needling in the appropriate Chinese meridians over "misplaced" needling. In this meta-analysis, the authors concluded that the efficacy of acupuncture for treatment of chronic pain remains doubtful.

Potential Harms and Costs. Reported complications of acupuncture include hematomas, infections (hepatitis B and *Staphylococcus aureus*), pneumothorax, and spinal nerve and spinal cord injuries due to buried needles migrating to the spinal cord.[215-220] In addition, the panel offered the opinion that needle insertion treatments involve some discomfort. Costs of acupuncture and other dry needling treatments vary depending on the number of treatment visits.

Summary of Findings. No studies were found evaluating efficacy of acupuncture in patients with acute low back problems. In three of the six RCTs evaluating efficacy for chronic low back problems, outcomes were better for the acupuncture group than for nontreatment control groups. All studies had methodologic flaws. Acupuncture was also found to have risks of significant complications.

Activity Modification

Activity Recommendations

Panel findings and recommendations:

- Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting. (Strength of Evidence = D.)
- Activity recommendations for the employed patient with acute low back symptoms need to consider the patient's age and general health, and the physical demands of required job tasks. (Strength of Evidence = D.)

Patients with acute low back problems frequently seek advice from clinicians about the physical activities they can "safely" perform. Employed patients, or their employers, also often ask health care providers to recommend work restrictions that will allow the patient to remain on the job during an episode of acute low back symptoms. Activity modifications are aimed at allowing the patient with an acute low back problem to achieve a tolerable comfort level while continuing adequate physical activity to avoid debilitation. The overall goal is to aid recovery while disrupting daily activities as little as possible.

Literature Reviewed. Of the articles screened dealing with work and other activity modifications for patients with acute low back problems, none met established panel review criteria for adequate evidence about efficacy. However, eight articles were considered by the panel to contain useful information on these issues.[221-228]

Evidence on Efficacy. A number of epidemiological studies have looked at risk factors associated with developing acute low back problems. Although there is no clear consensus on the role of these factors, several

studies have identified an increased incidence of low back problems among individuals whose work involves heavy or repetitive lifting, exposure to total body vibration (from vehicles or industrial machinery), asymmetric postures, and postures sustained for long periods of time.[221,229-231]

Other biomechanical research suggests that certain postures and activities increase the mechanical stress on the spine.[221,232-235] It is not clear whether these mechanical stresses are the cause of low back problems. However, once symptoms are present, mechanical stresses correlate with worsening of symptoms. Prolonged sitting and postures that involve bending and twisting have been shown to increase the mechanical stress on the spine according to pressure measurements in lumbar intervertebral discs. Heavy lifting also appears to increase mechanical stress on the spine, but this stress can be reduced if the lifted object is held close to the body rather than at arm's length.

A "lifting equation" to calculate appropriate lifting limits for various tasks was part of a guideline developed in 1981 by the National Institute of Occupational Safety and Health[236] and revised more recently.[228] Unfortunately, the ability of the guideline to reduce the incidence of low back problems has yet to be directly validated. Other ergonomic guidelines for safe lifting have been reviewed by Dul and Hildebrandt.[234]

Summary of Findings. While scientific information is limited, the panel felt that activity modifications represented an important practical issue for the clinician. The panel's recommendations are based on their interpretation of the available scientific data. Patients with acute low back problems can be advised to limit temporarily any heavy lifting, prolonged sitting, and bending or twisting the back since these activities have been shown to increase mechanical stress on the spine.

In recommending activity modifications for patients who work, the clinician may find it helpful to obtain from the employer a description of the physical demands of required job tasks. The nature and duration of limitations will depend on the clinical status of the patient and the physical requirements of the job. Activity modifications must be time-limited, clear to both patient and employer, and reviewed by the clinician on a regular basis.

Several ergonomic guidelines on lifting and materials-handling tasks are available to help the clinician provide ranges of activity alterations at work. These guidelines are based on various biomechanical assumptions and theoretical equations to build a margin of safety for individuals who have to lift at work. It should be remembered that such guidelines were developed for otherwise healthy workers and are therefore of limited use in making strict recommendations. None of these guidelines has been adequately tested to see if adherence will reduce the occurrence of low back problems.

The panel recommends that clinicians help patients establish activity goals, in consultation with their employer when applicable. Such goals are particularly important for the small percentage of patients who are still not

able to overcome activity intolerance after 1 to 2 months of symptoms. Since nonphysical f...tors, such as emotional distress or low work satisfaction, may ...fect an individual's symptoms and response to treatment, activit... can help keep attention focused on the expected return to full functional status and emphasize physical conditioning to improve activity tolerance.

Bed Rest

Panel findings and recommendations:

- A gradual return to normal activities is more effective than prolonged bed rest for treating acute low back problems. (Strength of Evidence = B.)
- Prolonged bed rest for more than 4 days may lead to debilitation and is not recommended for treating acute low back problems. (Strength of Evidence = B.)
- The majority of low back patients will not require bed rest. Bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of primarily leg pain. (Strength of Evidence = D.)

Bed rest is a frequently used treatment for acute low back pain. The therapeutic objective is to relieve symptoms by reducing intradiscal pressure and/or pressure on nerve roots. Studies have shown that intradiscal pressures are lowest when subjects are lying supine in the semi-Fowler position, on the back with hips and knees moderately flexed.[4]

Literature Reviewed. Of 12 articles screened for this topic, 5 reporting on 4 RCTs met criteria for review.[illegible] All these studies evaluated patients with acute low back problems. Other articles contained information used by the panel, but did not meet selection criteria.[illegible]

Evidence on Efficacy. Evidence is limited regarding efficacy of bed rest versus no treatment for patients with acute low back problems. One study involving military recruits compared forced bed rest to an alternative treatment of forced ambulation.[111] Although the bed rest group returned to full activity sooner, methodological problems with this study made interpretation difficult. Outcome assessments were not blinded, and patients in the hospitalized group were deprived of their peer-group activities, possibly confounding results. Two articles compared groups receiving either a recommendation for bed rest (of at least 4 days duration) or some other treatment (such as exercise, education, or manipulation) but no bed rest recommendation.[illegible] These two articles found no statistically significant differences between bed rest and other treatment modalities. Bed rest of more than 4 days and the resulting deactivation were worse for patients than a gradual return to normal levels of activity. Deyo, Diehl, and Rosenthal[229] compared two groups receiving recommendations for either 2 days or 7 days of bed rest. No differences were found between the groups in pain relief or in time to resumption of normal activities, except for earlier return to work in the 2-day group for those employed at baseline.

One problem with these s...s ... that the actual amount of bed rest reported by the subjects often ...ed greatly from the amount recommended. Deyo, Diehl, and Rosenthal[229] found that 74 percent of the 99 subjects assigned to the 7-day bed rest group reported fewer than 7 days of actual bed rest. The study reported by Evans, Gilbert, Taylor, et al.[77] and Gilbert, Taylor, Hildebrand, et al.[106] found that subjects who did not receive a bed rest recommendation also reported trying bed rest, but the duration was less than for the group receiving the recommendation.

Potential Harms and Costs. Potential physical side effects from prolonged bed rest are many, including muscle atrophy (1.0 to 1.5 percent of muscle mass lost per day), cardiopulmonary deconditioning (15-percent loss in aerobic capacity in 10 days), bone mineral loss with hypercalcemia and hypercalciuria, and the risk of thromboembolism.[330] There are also social side effects, such as perception of severe illness and economic loss due to increased time lost from work.[301]

Summary of Findings. There is no evidence to support the efficacy of bed rest compared with no treatment in patients with acute low back problems. Deactivation resulting from prolonged bed rest (more than 2 to 4 days) appears to be worse for patients than a gradual return to normal levels of activity.

Exercise

Panel recommendations and findings:

- Low-stress aerobic exercise can prevent debilitation due to inactivity during the first month of symptoms and thereafter may help to return patients to the highest level of functioning appropriate to their circumstances. (Strength of Evidence = C.)
- Aerobic (endurance) exercise programs, which minimally stress the back (walking, biking, or swimming), can be started during the first 2 weeks for most patients with acute low back problems. (Strength of Evidence = D.)
- Conditioning exercises for trunk muscles (especially back extensors), gradually increased, are helpful for patients with acute low back problems, especially if symptoms persist. During the first 2 weeks, these exercises may aggravate symptoms since they mechanically stress the back more than endurance exercises. (Strength of Evidence = C.)
- Back-specific exercise machines provide no apparent benefit over traditional exercise in the treatment of patients with acute low back problems. (Strength of Evidence = D.)
- Evidence does not support stretching of the back muscles in the treatment of patients with acute low back problems. (Strength of Evidence = D.)

- Recommended exercise quotas that are gradually increased result in better outcomes than telling patients to stop exercising if pain occurs. (Strength of Evidence = C.)

Various types of exercise programs have been advocated for patients with low back problems. The most commonly studied types focus on back flexion, back extension, generalized strengthening, endurance (aerobic conditioning), stretching, or some combination of these. Authors also reported exercises for low back problems as dynamic (isotonic) and static (isometric). Most of these exercises can be either taught to the patient for home use or performed under supervision in a clinical setting. Commonly reported therapeutic objectives of exercise programs for low back problems are improvements in endurance, muscle strength, and flexibility presumably leading to reduced symptoms, improved level of functioning, and fewer or less severe future back problems.

Literature Reviewed. Of 92 articles screened, 20 RCTs met criteria for review.[illegible]

Other articles contained information used by the panel, but did not meet article selection criteria.[illegible]

Only six of the articles reviewed involved studies of exercise as a treatment for patients with acute low back problems.[illegible]

Two other studies evaluated the efficacy of exercises for preventing or reducing the impact of low back problems in workers whose jobs involved frequent lifting.[illegible] The remaining articles all evaluated exercise as a treatment for groups that contained only patients with chronic pain or a mix of patients with acute and chronic problems. These were given less weight by the panel as there were enough studies using patients with acute low back problems.

Evidence on Efficacy. Of the six articles evaluating patients with acute low back problems, only one was considered well designed.[43] Swedish auto workers who had been off work for 6 weeks due to low back problems were randomized to either a control group with no recommendations for exercise or an exercise group with a program of gradually increased aerobic and back-strengthening exercises. At 1-year followup, patients in the exercise group had lost significantly less time from work due to back pain and had achieved a significantly higher level of fitness compared with the control group.

The other five articles dealing with acute low back problems included interventions that made the effect of exercise difficult to determine.[illegible]

Stankovic and Johnell[illegible] compared McKenzie extension exercises to a 45-minute educational session and found that the exercise group stopped medication use earlier and reported more pain relief and fewer days off work. Evans, Gilbert, Taylor, et al.[77] found that patients who received a flexion exercise program plus a 30-minute educational program stopped using medication sooner than did patients in bed rest and control groups. However, no differences were found between groups in reported degree of pain relief or activities of daily living.

The other three of these five studies showed no significant differences in outcomes between the treatment groups.[illegible]

Davies, Gibson, and Tester[illegible] compared groups receiving short-term diathermy and either extension or flexion exercises. Zylbergold and Piper[illegible] compared flexion exercises to manual therapy in combination with home back care instructions. Coxhead, Meade, Inskip, et al.[illegible] compared groups receiving various combinations of exercise (not otherwise specified), traction, manipulation, and lumbar corset use in a multifactorial study with 16 cells.

In summary, the six studies, which evaluated exercise for treating acute low back problems, used different forms of flexion or extension exercises, different treatment or control groups, different outcome measures, and different assessment periods. For this reason, no attempt was made to quantitatively combine these data.

As noted previously, two studies evaluated exercise for preventing acute or recurrent episodes of low back problems. Gundewall, Liljeqvist, and Hansson,[illegible] in a RCT, evaluated 60 nursing personnel working at a geriatric hospital. Subjects were randomized to receive either no intervention or a supervised exercise program during work six times per month for 13 months (emphasizing isometric and dynamic exercises strengthening the back extensor muscles).

At the end of the study, the exercise group had a significantly lower incidence of new low back problem episodes when compared with the control group (4 percent compared with 38 percent), fewer days lost from work, fewer days with back pain complaints, and a lower average duration of low back pain complaints. Trunk extensor strength measured with a spring gauge was not different between groups at the start of the study, but at the end of the study average trunk strength was significantly greater in the exercise group compared with the control group. The authors noted that the exercise group did receive more attention than the control group, which could account for some of the positive effect. Results were not reported separately for those with and without prior low back problems.

In the second study, Kellett, Kellett, and Nordholm,[illegible] in a RCT, evaluated 60 workers at a kitchen cabinet manufacturing company in Sweden. All were working at the start of the study and reported having either current or prior back pain. Subjects were randomly assigned to a control group or an exercise group. The exercise group was offered an exercise program at work once per week (30 minutes of aerobic movements of the arms, legs, and trunk followed by 10 minutes of relaxation) and were asked to do 30 minutes of aerobic exercise (such as walking, jogging, or cycling) on their own at least once per week.

Although subjects in the exercise group were encouraged to progressively increase their effort level during exercise, no direct measures of exertion (such as heart rate) were recorded. The exercise group was also

given lectures about back problems and proper lifting techniques. There were no signific[illegible]ferences between exercise and control groups in incidence rates [illegible] lost from work for episodes of back pain in the 1.5 years before [illegible]ntervention. The incidence rate and days lost from work for episodes of back pain decreased in the exercise group during the subsequent 1.5-year intervention period. In the control group, absenteeism attributable to back pain increased during the intervention period. There were no significant differences, either before or after the study, between groups in cardiovascular fitness as measured by a suboptimal bicycle ergometer.

Deyo[132] remarked that, although there seems to be a consensus among experts that exercise plays a major role in the treatment of low back symptoms, most treatment programs prescribe a combination of exercises and there is little agreement on specific regimens. He also offered an opinion that additional benefits of aerobic exercise may include weight loss and favorable psychological effects, such as reduction of anxiety and depression. Other studies have shown that patients improve faster when given specific quotas of exercises to do rather than being told to stop exercise when it produces pain.[82,84]

One study[131] found a back-specific exercise machine (the B-200) does not provide added benefit over traditional exercise in improving the objective back strength and flexibility (as measured by functional lifting capacity) of low back patients.

Potential Harms and Costs. Potential harms of exercise are usually not discussed. However, one RCT found that extension exercises caused increased symptoms in chronic low back pain patients.[136] Another study suggests that abdominal flexion (Williams flexion) exercises and stretching can increase mechanical stress on the spine as observed by intradiscal pressure measurements.[143]

Many methods have been proposed to evaluate mechanical stress on the back in different postures and activities.[82,128,134,141,147-150,152] A biomechanical model by Schultz directly correlates with in vivo measurements of intradiscal pressure and myoelectric signals.[82] The measurements of relative stress on the spine during postures and activities generally relate to increased and decreased symptoms experienced by patients with back problems. Thus, this information can be used for recommendations about safety and altering activity.

The costs of exercise programs can vary depending upon the setting. Those performed at home are inexpensive, whereas those done in supervised clinical settings are more costly. Exercise programs using back-specific computerized exercise machines can be very expensive. No studies meeting review criteria were found that provided evidence of any of these exercise settings being more effective than the others.

Summary of Findings. There are only a few RCTs that have evaluated exercise as a treatment for acute low back problems, and these are limited by small numbers of patients and inadequate descriptions of

specific exercise regimens. The one well-designed RCT of patients limited for less than 3 months by low [illegible] symptoms found that a program of gradually increased aerobic [illegible] k-strengthening exercises was superior to doing no exercise at all.[82]

Exercise programs aimed at improving general endurance (aerobic fitness) and muscular strength (especially of the back and abdomen) have been shown in some published studies to benefit patients with acute low back problems. No evidence supports stretching as effective treatment for acute low back problems. The panel offered the opinion that patients with acute low back problems would benefit from exercise programs if endurance programs are started early, using exercises that cause minimal mechanical stress on the back; if patients are given set exercise quotas gradually increased with time; and if later strengthening programs are individualized based on the level of activity to which patients wish to return. The panel suggested that the early goal of exercise programs is to prevent debilitation due to inactivity and then to improve activity tolerance to return patients to their highest level of functioning as soon as possible.